EXHIBIT F

01

KATHRYN E. CORBET and	:	SUPERIOR COURT OF NEW JERSEY
ERIC R. CORBET,	:	LAW DIVISION - BERGEN COUNTY
Plaintiffs,	:	DOCKET NO. BER-L-14589-14 MCL
v.	:	
ETHICON, INC., ETHICON	:	MASTER DOCKET NO.
WOMEN'S HEALTH AND	:	BER-L-11575-14
UROLOGY, a Division of	:	
Ethicon, Inc.,	:	CIVIL ACTION
GYNECARE, JOHNSON &	:	In re Pelvic Mesh/Gynecare
JOHNSON, and JOHN DOES	:	Litigation
1-20,	:	Case No. 291 CT
Defendants.	:	

VIDEOTAPED DEPOSITION OF NICOLETTE S. HORBACH, M.D.

Washington, D.C.

December 23, 2015

10:00 a.m.

Reported by: Linda S. Kinkade RDR CRR RMR CSR

The following is the transcript of the videotaped deposition of NICOLETTE S. HORBACH, M.D. held at the offices of:

O'Melveny & Myers LLP
1625 I Street, NW
Washington, DC 20006

Taken pursuant to applicable Rules of Civil Procedure, before Linda S. Kinkade, Registered Diplomate Reporter, Certified Realtime Reporter, Registered Professional Reporter, Registered Merit Reporter and Certified Shorthand Reporter, as licensed by the State of California, and Notary Public, as commissioned by the District of Columbia.

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P R O C E E D I N G S

VIDEO SPECIALIST: We are on the record. The time now is 10:01. This marks the beginning of disc 1 for the videotaped deposition testimony of Dr. Nicolette S. Horbach, in the matter of Corbet versus Ethicon, et al. This case is pending in the Superior Court of New Jersey, Law Division, Bergen County, Master Docket No. BER-L-11575-14.

Today's date is December the 23rd, 2015. This deposition is being conducted at 1625 Eye Street, northwest, Washington, D.C.

Will all attorneys present please identify themselves and who they represent.

MR. GRAND: Jeffrey Grand on behalf of plaintiff Kathryn Corbet.

MS. WAHRENBERGER: Judith Wahrenberger on behalf of Ethicon, Johnson & Johnson.

MR. KOOPMANN: Barry Koopmann from Bowman and Brooke law firm on behalf of Ethicon and Johnson & Johnson.

VIDEO SPECIALIST: My name is Michael Gay. I am with Golkow Technologies. Our court reporter today is Linda Kinkade, also with Golkow Technologies, and will now swear in the witness.

NICOLETTE S. HORBACH, M.D.,

Having been first duly sworn, was thereafter examined and testified as follows:

VIDEO SPECIALIST: You may proceed.

EXAMINATION

BY MR. GRAND:

Q. Good morning, Dr. Horbach. My name is Jeffrey Grand. I represent plaintiff, Kathryn Corbet, and her husband, Eric Corbet.

Before we begin, have you been deposed before?

A. Yes, I have.

Q. Okay. How recently were you deposed?

A. I believe within a year or so, within the last year.

Q. Okay. I'm going to assume you know most of the ground rules for a deposition. I'm just going to tell you that, if you need a break at any time, let me know; I'll be happy to accommodate you. I would ask, if -- if we're in the middle of a question and an answer, that we complete it before you take a break, but if you need a break for any reason, let me know.

Also, if I ask a question that is unclear to you, please tell me and I will do my best to rephrase it. Also, because the court reporter needs to take down our questions and answers, I would ask that you try to avoid nodding in responses or hand gestures. I

will try to do the same.

Also, to the extent that -- I ask that you let me finish a question before you attempt to answer it. I know we all have a tendency in conversation to anticipate questions and answers, but I will do my best not to step on your answers, and I would ask that you do your best not to step on my questions. Okay?

A. That's fine. Yes.

Q. Okay. We had just discussed that you have been deposed before. Can you tell me -- I believe -- when the last time you were deposed?

A. I believe my last deposition was within the last year or so. It was in the Pamela Wicker versus Ethicon, J&J case where I was deposed by Mr. Adam Slater.

Q. Okay. And have you been deposed in any other mesh-related cases?

A. Yes. I was also deposed in the case of Connie Schubert, I believe is the last name, versus J&J, Ethicon, which was, I believe, also a Prolift case.

Q. Okay.

A. I've also -- I'm sorry. I've also been deposed in a medical malpractice case as a defense witness in -- two to three years ago in Atlanta,

Georgia.

Q. Okay. Any other cases you can think of?

A. Not regarding mesh.

Q. Okay.

MS. WAHRENBERGER: Just answer the question.

BY MR. GRAND:

Q. In the three mesh-related cases that you described, did you testify at trial in any of those cases?

A. No, I did not.

Q. Outside the context of a mesh-related case, have you served as an expert witness?

A. Yes, I have.

Q. Okay. When was the last time you did that?

A. I believe that the last time I served as a both treating physician and causal -- causation, I guess you call it -- physician, was within the last two or three years here in Montgomery County, Maryland.

Q. Okay. And what sort of case was that?

A. The -- I was a plaintiff's witness -- expert. The patient had developed a periclitoral cyst that a physician had removed the cyst and the patient subsequently became an orgasmic and sought my care to

try to see if I could repair the nerves. And she subsequently then went forward with a malpractice suit against the original surgeon.

Q. Okay. Thank you. Would it be fair to say that, outside the context of the three mesh-related cases you've already told me about, that your previous testimony in court cases has been with medical malpractice cases?

A. Yes, that's correct.

Q. Okay. Have you been an expert in any other drug or medical device litigation --

A. No --

Q. -- other than mesh?

A. No, I have not.

Q. Okay. Thank you. Doctor, we're going to mark as Exhibit 1 the deposition notice that was served in this case.

(Exhibit 1 was marked for identification.)

BY MR. GRAND:

Q. Doctor, have you seen this before?

A. Yes, I saw this several days ago.

Q. Okay. Did you read it?

A. Yes.

Q. Okay. Have you brought any of the materials requested in the notice with you today?

A. I brought materials that were -- that I have. Some of the requested materials I -- I don't ever keep copies of or I don't have copies of, so it's not really relevant.

MS. WAHRENBERGER: And for the record we have provided you with the thumb drive of some of the documents that are responsive to this notice to produce.

MR. GRAND: Okay. We'll mark that later. I assume you brought it to give to the court reporter?

MS. WAHRENBERGER: The thumb drive? Yes, we have it.

MR. GRAND: Yeah. Okay. Thank you. I appreciate that. I had requested that, and obviously that makes things easier.

BY MR. GRAND:

Q. Okay. Doctor, have you -- well, first off, let's just go quickly through the notice so I can get an understanding of what will be included on the thumb drive.

Can you turn to Exhibit A, which is the third page?

A. Yes.

Q. Okay. On the thumb drive that you brought with you today, will it contain any documents related

to your fees and billing in this case?

A. No, it will not.

Q. Is that because you haven't generated any invoices yet in this case?

A. Correct.

Q. Has your -- with respect to item 2, the CV, is the CV that's attached to your general report the most up-to-date CV you have?

A. I actually updated the CV a few days ago per this request, and I don't know whether you have that most recent copy. I had forwarded it to the attorneys, but I don't know whether you received it.

Q. Okay. I have not, but I appreciate that.

A. I have a copy here. Would you like -- I have a copy here, if you don't have.

MR. GRAND: Is it on the thumb drive? Could counsel confirm that?

MS. WAHRENBERGER: No. We have a hard copy here at the deposition.

MR. GRAND: Okay. Obviously I can't see it remotely, so --

THE WITNESS: There are very -- sorry. There are only a couple changes compared to I think what would have been on my original report.

BY MR. GRAND:

Q. Thank you. Can you describe those changes for me?

A. There is one additional publication that has come out in 2015 where I'm one of the coauthors.

Q. Okay. What's the name of that article?

A. The -- sorry. The article is called "Ureteral Compromise in Laparoscopic versus Vaginal Uterosacral Ligament Suspension."

Q. Okay. And what journal is that published in?

A. It's published in Female Pelvic Medicine and Reconstructive Surgery.

Q. Okay. Thank you. And I think you said there was another change --

A. The only other change --

Q. -- to the CV?

A. The only other change is that I will be serving as a expert reviewer for research grant applications for the NIH regarding the Pelvic Disorder Treatment Network grant fund applications.

Q. Okay. And is that an appointment by the NIH or is that something you had to apply for?

A. No, I was asked by the -- I was contacted and asked by the NIH to serve as a special reviewer. I've done that previously.

Q. Okay. Is that typically something that -- is there a term that's served for that or is that an indefinite role?

A. The appointment is for specific grant proposals, so it's specifically regarding this particular project for a five-year pelvic floor or Pelvic Disorder Treatment Network grants for the U.S.

Q. Okay. And what is a Pelvic Disorder Network?

A. The pelvic floor or Pelvic Disorder Treatment Network is a multicenter collaborative research program that the NIH funds with approximately eight to nine different sites around the country who pursue research in primarily prolapse but also involving stress urinary incontinence or other disorders of the pelvis.

Q. Okay. So I guess under this -- under the umbrella of this network, researchers will be submitting grant proposals to you to review?

A. Yes, that's correct.

Q. Okay. And will you be -- are you the sole reviewer or will this be in conjunction with other physicians?

A. Typically it is a committee that reviews the different proposals. In past experience the

committee had approximately six reviewers to review the proposals, score them, and then provide the NIH with feedback regarding the priority scoring for who should be funded.

Q. Okay. With respect to the committee of reviewers, are -- is it comprised of specialists in various areas?

A. Yes, the committee is typically comprised of individuals who may be urogynecologists like myself. I don't remember if there were any urologists. Epidemiologists would be potentially involved as well.

Q. I guess my question is, in your role, would you be comfortable signing off on all aspects of a proposal including clinical trial design?

MS. WAHRENBERGER: Objection to the form of the question. You can answer.

THE WITNESS: It would depend on the specifics of what the issues were whether or not I would be comfortable signing off on them.

BY MR. GRAND:

Q. But you don't hold yourself out as an epidemiologist, correct?

A. Correct.

Q. Okay. Do you hold yourself out as an

expert in clinical trial design?

MS. WAHRENBERGER: Objection to the form of the question. You can answer.

THE WITNESS: I feel that I have a fairly strong background and expertise in that particular area.

BY MR. GRAND:

Q. Have you designed randomized control clinical trials before?

A. I have been part of the process of designing them, yes.

Q. Okay. How many times have you participated in the process of designing a randomized control clinical trial?

A. I can't tell you the specific number. It was a little bit more during the early stages of my academic career, but a number of times, including submissions of NIH grants myself personally with me as the principal investigator.

Q. Okay. How many times?

A. I don't recall the specific number.

Q. Less than ten?

A. Yes.

Q. Less than five?

A. I don't know.

Q. You had said earlier that there are certain types of documents that you don't keep in your file. Could you describe those types of documents for me?

A. One of the things that was requested was photos of any mesh material that I have ever excised. I don't take photos intraoperatively. The specimen is sent to the pathologist for documentation and analysis.

Q. Okay. And have you conducted any research yourself in examining explants, mesh explants?

A. I'm not sure what you mean by "research." Microscopic or --

Q. Yeah. Well, let's start there. Have you examined microscopically mesh explants?

A. I have reviewed them with the pathologists in individual patients where I have removed the explants.

Q. Okay. And when was the last time you did that?

A. It's probably within the last 12 months or so. We're not having to explant quite as many meshes as we have done in past time periods, so it's a little less frequent now.

Q. Is it your practice to conduct a microscopic examination of all the mesh you explant?

A. It's my practice to send those for microscopic analysis and histology. The pathology department will in the majority of cases run the microscopic analysis. Occasionally they will -- I've had times where they haven't; they have just done gross identification of it.

Q. Okay. So how many times have you reviewed mesh explants under a microscope?

A. Dozens.

Q. Dozens? Do you keep any database or collection of records relating to that?

MS. WAHRENBERGER: Objection to the form of the question. You can answer it.

THE WITNESS: Database relating to what my findings are of the -- of that?

BY MR. GRAND:

Q. Yes.

A. No, I don't.

Q. Yeah. Okay. So any findings you may have had you would have been recorded in the patient's individual records?

A. Yes, they -- yes, they may have been recorded in the patient's individual records, yes.

Q. With respect -- what other types of documents would you not have in your file in

connection with this case?

MS. WAHRENBERGER: Referring to the notice to produce?

MR. GRAND: Yes.

THE WITNESS: The -- we talked previously about I have not submitted any invoices or bills for my services. We talked about the photographs. The -- I didn't really quite understand the number 7, any documents regarding any conversations I've had with anybody regarding mesh. That is a little bit broad and/or wasn't really clear to me what, if anything, I was supposed to produce for that.

BY MR. GRAND:

Q. Have you billed for your time in the Wicker case?

MS. WAHRENBERGER: Excuse me. Just before you move on, Mr. Grand, I know the doctor was still looking at Exhibit A. So if you want to know whether there are any other portions of Exhibit A that she would not keep in a file, you've interrupted her response.

MR. GRAND: I'm sorry. I thought she was done. She was silent. So it's a little hard for me to see.

MS. WAHRENBERGER: Okay.

BY MR. GRAND:

Q. I'm sorry, doctor. Please go on.

MS. WAHRENBERGER: All right.

THE WITNESS: Sorry. I was silently reviewing, going through to make sure that I had included any of this.

I think that the majority of this is listed in -- in either the thumb drive, the literature, et cetera. I have not communicated with any other defendants' experts, I believe was number 16. There isn't any communication for me to provide.

The number 15 is difficult for me to provide you for presentations or lectures, primarily because my computer that had any of that on it died within the last six or eight months, and I have no access to that, and I do not have any lectures that I've given since on the new computer.

I have testified in front of a Congressional hearing regarding funding for or trying to advocate for funding for research in our field, including urinary incontinence. I never received any transcript and wouldn't even have the faintest idea how to actually find that, and that was over ten years ago. So that part I, unfortunately, can't give you.

I think the rest of the information I have here

with me or it's on the thumb drive.

MS. WAHRENBERGER: Look at 17.

THE WITNESS: 17 is -- oh, 17, no, I do not advertise my services as an expert in any way or website or anything like that, no, I do not.

BY MR. GRAND:

Q. Are you finished, doctor?

A. I think I've gone through them all. If there's anything specifically, we can go back to it.

Q. Okay. Thank you. I think you can set that aside.

With respect to the Wicker case, have you billed for your time in that case?

A. No, I have not.

Q. And the Schubert case?

A. No, I have not. Much to my husband's chagrin, but, no, I have not.

Q. I'm sure defendants appreciate you providing your services for free.

When did you start working on the Wicker case?

MS. WAHRENBERGER: Wicker?

BY MR. GRAND:

Q. Yes.

A. You're asking about Wicker?

Q. Yes.

A. I believe it was sometime in 2012, where I was first contacted to determine if I would be interested in serving as an expert witness or expert reviewer, shall we say.

MS. WAHRENBERGER: You answered the question.

BY MR. GRAND:

Q. And when did you begin working on the Schubert case?

A. I believe the Schubert case was sometime in 2013.

Q. So you've been consulting with defendants since 2012 and have not billed them yet?

A. I'm not a very good business person. That's correct; I have not billed them yet.

Q. Have you entered into any consulting agreements with Ethicon?

A. I don't know whether this is considered consulting agreement or not where I'm serving as an expert. So obviously I have the agreement that I'm reviewing as an expert. In the past I have attended one focus-type group as a consultant but do not have any specific consulting agreement with Ethicon.

Q. Okay. And was that in 2001?

A. Yes, I believe so.

Q. Okay. Have you ever served as a proctor or a preceptor for Ethicon for any of its products?
A. No, I have not.
Q. Have you ever consulted with Ethicon in regards to any of its clinical trials of its products?
A. No, I have not.
Q. Other than as a litigation consultant and the focus group from 2001, which you've mentioned, have you consulted with Ethicon in any way?
A. No, I have not.
Q. Over the years have you had any interaction with any employees from Ethicon or developed any professional relationships with employees from Ethicon?
MS. WAHRENBERGER: Beyond what we've already discussed?
MR. GRAND: Yes.
MS. WAHRENBERGER: Focus group and the expert work?
MR. GRAND: Yes.
THE WITNESS: I have seen Ethicon reps at our national meeting in the exhibits hall and/or have seen them at times in the operating room.
BY MR. GRAND:
Q. You had Ethicon reps in the operating room

when you were performing surgeries?

A. I don't know that I've had them actually in the operating room with me rather than in the sort of general operating area. I -- Ethicon also has other products that we use in the operating room that are not mesh or related for incontinence, et cetera, so some of my dealings with the Ethicon reps may be more related to that versus this particular thing, but I do not recall anytime where I've specifically had an Ethicon rep in the operating room when I was performing something like a TVT.

Q. Okay. Why would you have an Ethicon representative in the operating room for any reason?

MS. WAHRENBERGER: Well, objection. I think you're mischaracterizing her testimony. She said she didn't.

MR. GRAND: Well, she started out saying she's had them in the operating room, so --

THE WITNESS: No, that's -- no, that's -- I'm sorry. Then I mis -- I misspoke or misunderstood. I've had them in the overall operating -- I've interacted with them in the overall operating area in like the hallway, or occasionally when we are looking at a new product or the hospital is looking at a new product, they will have them in the hallway to show

you what this cauterizing device does versus the one we traditionally use, if they are negotiating contracts, things like that. So it was more -- that's sort of what I mean from the operating room rather than specifically in the operating room itself.

BY MR. GRAND:

Q. Okay. Thank you. Have you had Ethicon sales reps visit you at your office or at your practice?

A. Possibly, but I don't know for sure nor do I know really who they are or what their names are.

Q. Can you provide the names of any Ethicon employees with whom you've interacted over the years?

A. No, I don't have that -- that type of relationship nor has it been a continuous person at any point.

Q. Have you attended any meetings sponsored by Ethicon over the years?

A. I'm not quite sure what you mean. I mean, the focus group was, I suppose, sponsored by Ethicon. Our national meetings, whether at AUGS or SGS, occasionally these -- those companies will be a, I don't know, a contributor or whatever you say, I don't know what you call it, for helping to underwrite maybe the costs of the meeting. So in that sense I probably

have attended something, but nothing specifically where I've gone just for that particular meeting and that's just sponsored by Ethicon.

Q. Have you ever spoken or given presentations about Ethicon products?

A. Not specifically regarding Ethicon products. I -- yeah, not specifically regarding Ethicon products. I may have discussed that Prolift was a treatment option for prolapse when I'm giving a generalized discussion about prolapse in a grand round, something like that, but ...

Q. Do you know whether Ethicon has ever promoted you to patients as a surgeon who uses their products such as the TVT or the Prolift?

A. I do not know that.

Q. Have you heard of the Find-a-Doc program?

A. Yes, I have, and I'm not listed on that, at least when I just recently looked, because that's the first time I've heard about it.

Q. Have you -- do you know if you've ever been listed on it?

A. No, I don't.

Q. Doctor, do you currently use the TVT Retropubic device?

A. No.

Q. When was the last time you implanted a TVT Retropubic?

A. It's probably been over five years, as I use the TVT Exact at this point now.

Q. When was the first time you implanted a TVT Retropubic?

A. I believe it was sometime in 2002 or 2003.

Q. In 2003 did you begin using Boston Scientific slings exclusively?

A. Boston Scientific?

Q. Yes.

A. No, not that I know of or not that I recall.

Q. How often did you -- was the TVT -- was the TVT Retropubic your preferred sling for patients at any time?

A. Yes, in the early times when I first started doing the minimally invasive sling procedures.

Q. That would be 2002?

A. 2002, 2003, as I mentioned.

Q. And what other midurethral slings did you use at that time?

A. The only midurethral slings that I have used are the TVT Retropubic, the TVT Exact, the Boston Scientific Advantage, and I've implanted one SPARC

when the hospital had none of the other ones that I wanted to use -- they had run out.

Q. Prior to using TVT Exact, which I believe you said you started using that about five years ago, was the Boston Scientific Advantage your preferred sling?

A. I don't remember exactly when I transitioned to using the TVT Exact, but there was a period of time in the middle where I did use Boston Scientific more often.

Q. Would it be fair to say that from the time you started using the TVT in 2002 or 2003, that you've used it with decreasing frequency up until the time you started using the TVT Exact?

MS. WAHRENBERGER: Objection to the form of the question. You can answer.

THE WITNESS: If I understand your question to be that have I used the TVT Retropubic with decreasing frequency, there was a period of time, yes, where I transitioned to not using it. So I guess that's decreasing frequency.

BY MR. GRAND:

Q. And by that you mean you transitioned to the Boston Scientific sling, correct?

A. Boston Scientific sling or the TVT Exact.

Q. What treatment options do you presently offer for a patient with stress urinary incontinence?

A. Are you asking surgical or nonsurgical or both or ...

Q. Let's go through both.

A. I first discuss with patients nonsurgical treatment options. That includes evaluating and adjusting behavioral habits, such as fluid intake, frequency of voiding, habits relative to voiding before exercise, other changes that I think would improve their stress incontinence.

I offer them the alternative that, if it's not bothering them enough, that they don't necessarily have to treat it at all. I offer them trying to use something like pelvic floor exercises to improve their muscular tone, if they are already able to at least generate some type of pelvic floor contraction and their symptoms are -- tend to be more isolated for leakage that occurs with cough or sneeze, more brief exposure for a leakage episode rather than per se exercise.

I offer them vaginal support devices, whether that is a incontinence ring, incontinence dish, ring pessaries, a simple o.b. brand tampon to provide support for the urethra.

Those are -- I don't use medications for stress incontinence, since duloxetine, although it has effectiveness, is almost never covered by their insurance plan, and the out-of-pocket expenses are typically too high for them to pay out of pocket.

That would include primarily the surgical -- I mean nonsurgical issues. I do tell them, if they are leaking with running only, that perhaps swimming might be a better exercise since it's going to reduce their likelihood of leaking.

Then I discuss with them surgical treatment options as well. The surgical treatment options that I include are periurethral bulking agents, midurethral sling procedures. I discuss with them -- oh, actually suburethral plication, which would be more like a traditional Kelley-Kennedy type plication with sutures.

I discuss with them Burch or retropubic urethropexies. I at times will discuss with patients an autologous usually rectus fascial sling in select patients where I think that that type of option is appropriate.

Q. Do you recommend midurethral slings as a first-line option for your patients?

A. First-line surgical option?

Q. Strike that. Let me go back a little bit.

You typically recommend a surgical treatment as your first-line option for patients with SUI.

A. No.

Q. Would it be fair to say that you would counsel them as to more conservative treatments before recommending surgery?

A. Yes.

Q. With respect to surgical treatments, do you recommend midurethral slings as a first-line treatment option?

A. It depends on the patient's specific situation, medical factors, anatomy, other risk factors, whether or not I would choose that as my first choice -- first-line recommendation.

Q. Okay. Under what circumstances would you not recommend a midurethral sling as a first-line treatment option?

A. If a patient has a history of treatment for a urethral diverticulum or urethral fistula; if she has had a prior sling procedure with a synthetic material and has had problems with it or had it partially resected; if a patient has no evidence of urethral hypermobility on her examination; if a patient has significant voiding dysfunction or

elevated post-void residual; if a patient has mixed urinary incontinence with a primarily urge component more than a stress component. Those are typically the situations under which I would not suggest a midurethral sling.

Q. So if a patient came to you and had mixed urinary incontinence but their primary symptoms were more urge incontinence rather than stress urinary incontinence, you would not recommend a midurethral sling?

MS. WAHRENBERGER: Objection to the form of the question. You can answer.

THE WITNESS: I would not recommend that as my primary -- necessarily as my primary approach. I might discuss with them an option, but I wouldn't necessarily say that's, you know, the number one choice that I would end up doing right off the bat.

BY MR. GRAND:

Q. What would be your number one choice doing right off the bat?

MS. WAHRENBERGER: With urge incontinence?

THE WITNESS: If a patient had mixed incontinence with primarily a urge component, actually I would try to treat the urge incontinence and resolve that before I would even consider any type of surgical

intervention for the stress incontinence. As some patients, if you resolve the urge incontinence, the stress incontinence component is fairly minor and they may not choose any type of further treatment.

BY MR. GRAND:

Q. Can a midurethral sling worsen urge incontinence?

A. Yes, it can in some women.

Q. And when you make a recommendation to a patient for a surgical option to treat their stress urinary incontinence, you're weighing the risks and benefits of that procedure for that patient, correct?

A. Yes, for -- that's true for any surgical patient you're weighing risks and benefits.

Q. And when you recommend a mesh procedure as opposed to other surgical options, that is in your view because one mesh may be preferable for that patient than another, correct?

MS. WAHRENBERGER: Objection to the form of the question. You can answer.

BY MR. GRAND:

Q. Strike that. Let me re-ask it.

A. Yeah, I'm not sure I understood that.

Q. It was a poor question. I'll try to do better.

When you recommend a mesh procedure to a patient as opposed to other surgical options, that's because in your view the mesh product is a better option for them than another surgical procedure, correct?

MS. WAHRENBERGER: Objection to the form of the question. You can answer it.

THE WITNESS: It's not necessarily that the mesh product is a better option. It's the overall surgical procedure is a better option for that patient versus perhaps the alternative procedures.

BY MR. GRAND:

Q. And when you implant a mesh device, you're not -- it is a procedure as well, correct?

MS. WAHRENBERGER: Objection to the form of the question. You can answer.

THE WITNESS: To implant a mesh device is a procedure. It is a surgery, yes.

BY MR. GRAND:

Q. And it's a procedure that is different because you're using mesh than other surgical procedures to correct stress urinary incontinence, correct?

A. It is a different procedure for many reasons, including the fact that you are implanting a

mesh product, but that's not the only difference between those minimally invasive slings and other surgeries.

Q. Okay. Thank you. And if you were to recommend one mesh product to a patient over another mesh product, is that because you view one product as being more beneficial to that patient than the other?

MS. WAHRENBERGER: Objection to the form of the question. You can answer.

THE WITNESS: I would recommend one type of midurethral -- I may recommend -- let me think.

I don't necessarily recommend to a patient one type of midurethral sling over another type of midurethral sling. I choose to do one type of midurethral sling procedure because of the overall components involved with that procedure.

BY MR. GRAND:

Q. Is that another way of saying you prefer certain meshes to others?

MS. WAHRENBERGER: Objection to the form of the question.

THE WITNESS: Again, it's not just the mesh issue. There are other things about the device or the implantation that I might prefer from one type of procedure versus another, such as, you know, a

bottom-up versus a top-down procedure, a retropubic versus an obturator procedure, the size of trocars, the color of the mesh, the types of sheaths, I mean, the handle on the insertion needle. All of those I factor in for me when I am choosing a midurethral sling procedure.

BY MR. GRAND:

Q. Okay. And is that because the benefit/risk profile for one procedure may be better for a patient than for -- than another mesh procedure?

MS. WAHRENBERGER: Objection to the form of the question. You can answer.

THE WITNESS: I don't think the choice of which midurethral sling procedure I do is significantly affected by that component of whether this mesh is better than that mesh. I think it's more based on the totality of the procedure itself rather than on specifically the mesh as the driving force.

BY MR. GRAND:

Q. Do you view certain mesh products or procedures as being better than others for sexually active patients?

A. In my experience I typically prefer a retropubic midurethral sling versus a transobturator sling in someone who might be sexually active or

interested in future sexual activity.

Q. Do you view certain mesh products or procedures as being better for physically active patients?

A. I think that perhaps the same preference, as I just stated, that I would probably, again, prefer a retropubic approach versus a transobturator approach for someone who was physically active.

Q. Doctor, how many TVT Retropubics have you implanted?

A. I --

MS. WAHRENBERGER: Could I ask for clarification? Are you including Exact in that since it is a retropubic?

MR. GRAND: No. I'm including the TVT Retropubic which is at issue in this case.

MS. WAHRENBERGER: Okay.

THE WITNESS: I can't give you a specific number because that was -- it's been a number of years since I have. I tend to implant approximately a hundred plus midurethral slings per year myself, and in my overall practice of the three individuals we usually implant between three hundred and four hundred midurethral slings per year. In particular --

BY MR. GRAND:

Q. You say you each do? I'm sorry. I didn't mean to interrupt you.

A. No, our practice as a group of three of us usually implant between three hundred and four hundred midurethral sling procedures per year. One of my partners does pretty much exclusively retropubic slings based on his personal preference of the whole device and the handle and the needles, and one partner is more just, you know, TVT Exact. I mean, I think it's partially based on -- again, it's not just the mesh that you factor in in making your decision.

Q. Can you make an estimate as to how many TVT Retropubics you implanted in 2002?

A. In 2002 itself? No, I wouldn't have a clue. I would be just guessing.

Q. How about in 2003?

A. Again, that was a long enough time period ago that I can't give you the specifics of how many procedures I would have done at that point. I think that the transition for me of using midurethral slings as my primary treatment began in that 2002 to 2003 time period.

Ultimately, after a couple years, I used midurethral slings fairly exclusively rather than Burch procedures or traditional suburethral slings.

So certainly by about 2004-ish, maybe 2004-2005, I probably was, you know, 99% of the incontinence procedures that I was doing at that time would have been midurethral slings. And during that time period the bulk of them at that point would have been probably the Retropubic TVT, if I recall exactly.

Q. Do you know how many of your -- of the patients in whom you've implanted TVT Retropubics have returned to you with erosions?

A. I have not seen any patient with an erosion from a TVT Retropubic that I've implanted. I've never had an erosion -- to me at least.

Q. Okay. And is that qualification based on the fact that there may be patients who have gone -- who have sought treatment elsewhere?

A. Correct. They may have moved to Florida, which a lot of my patients do when they retire, or someplace else, but I have not received request of records from any physicians for -- that I've implanted the TVT Retropubic on -- can't recall any request of records that I would have received that would have, you know, indicated transfer of care. Again, that was a long time ago, so it's hard to remember specifically.

Q. And would that be true -- what about

dyspareunia? Do you know how many of your patients in whom you've implanted the TVT Retropubic have returned to you with dyspareunia?

A. I have seen a few patients who will present with dyspareunia. The majority of those patients have had concomitant other procedures done at the same time as the midurethral sling. And I certainly know that I have not had to go back and remove any -- any midurethral sling regardless of which product for pain or dyspareunia, none -- not that I have implanted.

Q. Have you had to remove a TVT-R that you've implanted for any other reason?

A. I have reoperated to release a TVT or midurethral sling in a small number of women because of, let's say, voiding difficulties, either slow stream or perhaps elevated post-void residuals. I have had that where I've primarily divided the sling rather than actually removed the sling.

Q. And how many times have you had to do that?

A. I have done that in 12 patients, although I can't give you the specifics of which exact sling they were. It's more likely -- yeah, I'm not sure which specific slings that they had done.

Q. How many Boston Scientific slings have you implanted over the years?

A. I don't know.

Q. Hundreds?

A. Yeah, probably hundreds, in that category.

Q. When was the last time you implanted a Boston Scientific sling?

A. Within the last two weeks or so.

Q. Do you track complications among patients in whom you've implanted the TVT Retropubic device? Strike that.

Do you track complications among any of your patients in whom you've implanted midurethral slings?

A. Yes.

Q. Do you keep a database?

A. I keep a record of those particular patients with these particular complications, yes.

Q. And in what manner is that kept? Is that kept, for example, on a spreadsheet or do you have a specific database?

A. That type of record is not -- I'm not so computer savvy, so it's actually the old-fashioned way on a piece of paper so -- that I keep a list of patients who I've had as -- if I've had an erosion, if I've had to return to the operating room for a release of a sling for voiding issues.

MR. GRAND: Okay. Counsel, we're going to

request a copy of that, omitting any patient specific -- patient identifying information.

MS. WAHRENBERGER: Please put it in writing.

THE WITNESS: I'm not sure how I can provide you that --

MS. WAHRENBERGER: We'll worry about that.

THE WITNESS: -- information without patient identification, but, okay.

MS. WAHRENBERGER: You make the request and we'll deal with it.

MR. GRAND: Your counsel --

BY MR. GRAND:

Q. Has defense counsel provided you with the names of any lawsuits in which you have been identified as either the implanting physician or the revising physician?

A. Yes.

Q. In that list was it identified for you in which cases you were the identifying -- whether you were the implanting physician or the revising physician?

A. The list did not identify which role I had, no.

Q. Okay. How many cases were on that list?

A. I received a list of two different -- two different lists, and the total number of patients on the list are 15.

Q. And when you say "two different lists," what was the difference between the lists?

A. I was told that one was New Jersey and one was West Virginia.

Q. Okay. And the total between both lists was 15?

A. Yes.

Q. And when you received this list, did you go look in your own records to see what, if any, of those -- if any of those claimants were patients in whom you had implanted an Ethicon device?

A. Yes.

Q. And how many of those patients -- how many of those claimants were ones in which you had implanted the device?

A. Well, there are different Ethicon devices, so that's going to make a difference. There were two out of the 13 that I did not implant; I was the person that reoperated --

Q. Revised?

A. Revised, thank you, I was trying to think of the word. -- revised the surgery, so two I know

for that. There were either two or three on the list that are Prolift patients. There are a number of them on the list who are sacrocolpopexy patients where I believe the mesh that was used was probably either a straight Prolene mesh years and years ago or a Gynemesh type of product, but they did not receive a midurethral sling or Prolift.

I think there were either four or five patients on the list who had received midurethral slings. I have not had time, since I just received the list recently, to determine which sling product was implanted.

Q. Thank you. With respect to -- strike that.

Did you ever receive any training from Ethicon with respect to implanting the TVT Retropubic?

A. No, I did not specifically from Ethicon.

Q. Who did you receive training from with respect to implanting the TVT-R?

A. My partner had been implanting the device for at least a year or more, and he and I scrubbed in the beginning together when I was doing my cases.

Q. And what's your partner's name?

A. Jeffrey Wellgoss.

Q. And so -- I just want to make sure I heard you correctly. Did you observe him do the procedure

or did you participate in doing the procedure with him?

A. Actually both, first observing him do the procedure, and then subsequently doing it with him with the two of us scrubbed together and watching how he did it, having him, you know, recommend how I would do it, yes.

Q. Okay. And did you do that more than once with him?

A. Yes.

MS. WAHRENBERGER: Objection.

THE WITNESS: Yes.

BY MR. GRAND:

Q. Okay. How many times did you observe or participate with him in doing a procedure before you did one yourself?

A. It was less than -- somewhere between probably three to five. I don't recall specifically. Again, it was a long time ago.

Q. At the time that you first implanted a TVT-R -- sorry, TVT Retropubic -- would you -- did you consider yourself to be an experienced pelvic floor surgeon?

A. Yes, I did at that time, yes. Still do.

Q. I wasn't questioning your experience,

doctor.

MS. WAHRENBERGER: Yes, you were.

MR. GRAND: Not at all, and I don't appreciate the comments, counsel.

MS. WAHRENBERGER: It's just what the question was. That's all right.

MR. GRAND: I asked her if at the time she considered herself one.

BY MR. GRAND:

Q. This is going back to 2003, correct?

A. Correct.

Q. Okay. Do you believe there is a learning curve associated with implanting the TVT Retropubic?

A. I think there's a learning curve with any surgical procedure, including that, yes.

Q. How many times did you need to perform the procedure before you felt proficient at it?

A. For me, I don't think that it took very many procedures before I felt comfortable in part because I had been doing sling procedures and needle suspension procedures for over 15 years previously, so that the dissection, the retropubic space and the passage of the instruments, tensioning of the sling, et cetera, was something that I was quite familiar with.

Q. Okay. Thank you. With respect to synthetic midurethral slings, was the TVT Retropubic the first one you had used?

A. The first synthetic midurethral sling, yes, not the first synthetic sling.

Q. Okay. Thank you.

MR. GRAND: Let's mark as Exhibit 2 your Expert General Report dated July 9, 2014.

(Exhibit 2 was marked for identification.)

MS. WAHRENBERGER: Before we start on that, may I take a quick break?

MR. GRAND: Absolutely. Why don't we take a ten-minute break.

VIDEO SPECIALIST: The time now is 11:18. We're going off the record. This is the end of disc 1.

(Proceedings recessed.)

VIDEO SPECIALIST: The time now is 11:35. We are back on the record. This is the beginning of disc 2.

BY MR. GRAND:

Q. Doctor, I believe before the break you were given what's been marked as Exhibit 2, which is your general report dated July 9th, 2014, correct?

A. Correct.

Q. When did you first begin working on this report?

A. Approximately a year prior to that time period.

Q. So roughly July 2013?

A. July, August, something around there, yes.

Q. And how many hours did you spend preparing this report?

A. The total number of hours is probably 60-ish or so.

Q. And what was your hourly rate for preparing your report?

A. I charge $500 an hour.

Q. And I'd like you to have what's marked as Exhibit 3 the December 15th, 2015 supplemental report that you prepared.

(Exhibit 3 was marked for identification.)

BY MR. GRAND:

Q. Do you see that?

A. Yes, I have it.

Q. Okay. And when did you begin working on that report, the report you now have in front of you dated December 15th?

A. It was probably three or so weeks ago, right around Thanksgiving.

Q. And how many hours would you say you spent preparing this report?

A. That one I can pretty much tell you -- 48 hours.

Q. And that's at the same rate of $500 per hour?

A. Yes.

Q. Doctor, in your report you've offered opinions about the risk/benefit profiles of the TVT Retropubic, correct?

A. Yes.

Q. Would you agree with me that for you to offer a valid opinion about the risk/benefit profile for the TVT Retropubic that you need to be familiar with each of the risks of the product?

MS. WAHRENBERGER: Objection, but you can answer.

THE WITNESS: Each of the, yeah, each of the significant or relevant risks, yes.

BY MR. GRAND:

Q. What do you mean by "relevant risks"?

A. I think that the risks that would be applicable to my decision as a clinician of whether or not this was a procedure that I wanted to offer and essentially do for my patients.

Q. Are there risks of the TVT Retropubic that you think are not relevant to that consideration?

A. I think there are risks that have been alleged in the plaintiff's experts' reports that I don't think are relevant risks in making my decision.

Q. To decide whether the risks are relevant or irrelevant, would you need to be familiar with those risks?

MS. WAHRENBERGER: Objection to the form of the question.

THE WITNESS: Yes, I would expect that's the case, yes.

BY MR. GRAND:

Q. In your report you've also expressed opinions about the adequacy of the warnings for the TVT Retropubic, correct?

A. Yes.

Q. Have you offered warnings opinions in litigation before?

A. Not that I can recall. Okay. Just making sure I understand your question. Have I offered testimony about the, whatever, appropriateness of written warnings in -- in testimony before; is that what you're asking?

Q. Yes.

A. Not relative to a product but relative to consents.

Q. You're talking about the consent process in MedMal cases that you've testified in?

A. Yes, that's a written warning or a discussion regarding warnings, risks of the procedures.

Q. Okay. Have you ever offered warning opinions in connection with drugs or medical devices in litigation before?

A. Yes, I have, relative to the Prolift in my prior two depositions.

Q. Have you testified in court concerning the adequacy of warnings for the Prolift?

A. No. As I said, I've not -- both cases have settled, so I have not been in court.

Q. Do you know whether the judges in those cases determined whether you were qualified to give such opinions?

A. I don't know that.

Q. In formulating your warnings opinions in this case what standards did you apply?

A. I applied the clinical standards for determining -- determining how much information is necessary or not necessary in a written document

versus the current information that was in the medical literature regarding the potential complications of incontinent surgeries with or without the use of other synthetic mesh materials.

Q. Okay. Whose clinical standards were those?

A. Those are the clinical standards based on my position in national organizations of having written guidelines for education and training. Those are based on my work with having been recognized as an expert by the American Board of Ob/Gyn, The American College of Obstetrics and Gynecology, the NIH, The American Urogynecologic Association, and -- so, yeah, I think that -- it's that type of expertise.

Q. Okay. So I didn't ask expertise. I'm asking about standards, doctor. Did you apply your own personal standards in deciding whether the labeling was adequate?

MS. WAHRENBERGER: Objection, asked and answered.

THE WITNESS: I applied --

BY MR. GRAND:

Q. You can answer.

A. I applied what I believed to be the clinical medical standards in the community -- in the medical community for our field.

Q. Okay. Are those published anywhere?
A. No.
Q. Did you consult any published standards in formulating your warnings opinions?
A. No.
Q. Did you consult any FDA guidance documents with respect to warnings for medical devices?
A. No.
Q. Did you look at any Ethicon internal standards for warnings on medical devices?
A. No.
Q. Did you review any testimony from Ethicon employees who had labeling responsibilities for the TVT?
A. I've seen some internal documents and/or email things going back and forth, but I don't know that I've specifically seen deposition testimony regarding Ethicon employees.
Q. Have you consulted with any drug or device company on product labeling for their products?
A. For product labeling? No.
Q. Have you ever been asked by a regulatory agency to consult with them on product or device labeling?
A. I know that I had at one point done some

work with the FDA regarding device issues, but I can't recall whether that part is -- was specifically part of it or not, and it was a long time ago.

Q. Do you remember the name of the device that was involved?

A. I don't know whether it was when we were evaluating Miniguard or one of the bladder neck prosthesis or whether it was something even outside of, you know, urogynecology. I seem to remember something; I just can't tell you the specifics.

Q. Did you consult any industry standards for medical device labeling?

A. No, I did not.

Q. Is your opinion regarding the adequacy of the labeling for the TVT Retropubic based on what you believe would be adequate in your own medical practice based on your own experience?

MS. WAHRENBERGER: Objection to the form of the question.

THE WITNESS: No.

BY MR. GRAND:

Q. You can answer.

What else did you base the adequacy -- what else did you base your opinions on regarding the adequacy of the TVT Retropubic labeling?

MS. WAHRENBERGER: Objection, asked and answered.

THE WITNESS: I think -- I think I have answered that, but the -- one aspect of the IFU states that physicians who are using this product or device to do a surgical procedure for stress incontinence specifically specifies that the implanting physician has experience, familiarity, understands the issues involved with the treatment of stress incontinence surgically and the issues involved with the use of a synthetic mesh product, and based on the literature that was available prior to -- at the time where the TVT Retropubic was being marketed or put out, essentially all of the risk issues that are involved with the TVT Retropubic were already known risk factors for either surgeries for stress incontinence with or without the use of a synthetic mesh.

Therefore, the physician who is implanting this, to be appropriately doing that surgery and especially having the expertise and treating stress incontinence and using mesh, would have been familiar -- even if they had never read a single portion of the IFU -- would have been familiar with those risks that were outlined in the original IFU or that the plaintiff's experts have said should have

been included in the IFU.

Q. Okay. Is -- are your warnings opinions in this case based on an assumption about what other doctors should have known?

MS. WAHRENBERGER: Objection to the form of the question.

THE WITNESS: Well, it's not -- I mean, the issue is your -- I mean, I obviously can't determine what is in someone's brain, but if you are implanting a mesh device and you're doing an incontinent surgery, then you shouldn't really be doing it unless you know those risks going in even based on the literature that was already out there that detailed the risks.

There isn't anything specifically different for the midurethral sling or the TVT Retropubic risks that had not already been addressed in the medical literature regarding stress incontinence surgery or mesh use.

BY MR. GRAND:

Q. What about contraction as a result of the mesh?

A. That was known in the literature from prior synthetic urethral slings -- prior synthetic suburethral slings that have been done starting in the early 1960s.

Q. Okay. So your warnings are premised on an assumption that all doctors would have been aware of all the literature out there, correct?

MS. WAHRENBERGER: Objection.

THE WITNESS: Again, the issue is that -- I mean, it's sort of -- somewhat of a ridiculous question in that the surgeon who is implanting this has to have the understanding and expertise of doing the surgery; otherwise, they shouldn't really be doing the surgery.

So that's not my position nor Ethicon's nor, you know, anyone else's position to tell the physician yes or no, you have the knowledge base. I mean, there's not a checklist that you have to go through saying do you know this, do you know this, do you know this before you can actually do an operation. That's dependent upon the individual physician making the personal assessment that they do or do not have that information.

And I don't think that it is the obligation of a company to ensure that the physician has that knowledge base to go forward with the surgery. That's really the role of a credentialing body of a hospital or a certification body for board certification. It's not the criteria of a company.

Q. Do you believe the company has an obligation to ensure that doctors are aware of all risks associated with the product and the procedure?

A. I think that the company has a responsibility to inform physicians of any risk that is a new or different risk than what is already out there in the literature regarding similar situations or similar procedures or materials.

Q. Okay. And that opinion is based on a premise that doctors have knowledge of what's out there in all the literature, correct?

MS. WAHRENBERGER: Objection to the form.

THE WITNESS: Again, you should not -- the doctors, if they are doing the procedure, shouldn't be doing the procedure if they don't have a knowledge about the literature and the data regarding the use of synthetic materials in pelvic reconstructive surgery. I'm not sure how I can answer the question any differently.

BY MR. GRAND:

Q. No, that's fine. Thank you.

Do you have opinions regarding the adequacy of the warnings contained in the TVT Retropubic patient brochures?

A. My determination about -- yes, I have an

opinion.

Q. Which brochures did you review?

A. I reviewed from the earliest ones up until the actually current one that is on the website at this particular time.

Q. You have not reviewed Mrs. Corbet's medical files, correct?

A. Not her entire medical files, no.

Q. You've reviewed some of her medical file?

A. Not the medical record itself. I've reviewed expert -- an expert report by Dr. Rosenzweig regarding her medical history and his IME.

Q. You're not intending to offer opinions specific to the Corbet case, are you?

A. I don't believe so.

Q. Do you understand that you haven't been offered as an expert in this case on the specifics of Kathryn Corbet's medical treatment, correct?

A. That's -- yes, that's why I said I believe so, I'm not going to be offering those opinions.

Q. And you don't know if Kathryn Corbet ever read a patient brochure, do you?

A. No, I do not.

Q. And you certainly -- if she did, you don't know which one she read, correct?

A. Correct.

Q. Do you have any knowledge as to the agreements between Ethicon and Professor Olmsted and his company?

A. I have not seen the agreement, no.

Q. Okay. Do you know any of the details of that interaction?

A. Only from, you know, very peripherally, that there was a relationship in the development and design of the TVT Retropubic.

Q. Do you intend to offer any opinions at trial on that agreement?

MS. WAHRENBERGER: Objection to the form of the question.

THE WITNESS: I don't think so.

BY MR. GRAND:

Q. You don't discuss that in your report at all, do you?

A. No.

Q. Okay. Have you been involved in any Ethicon clinical studies for any of its mesh products?

A. No.

Q. Are you familiar with the concept of financial bias in a clinical trial?

A. I'm familiar with the terminology, yes.

Q. What does financial bias in the context of the clinical trial mean to you?

A. Financial biased to me means that the researchers either conduct the trial or report the results of the trial in such a way that distorts/ changes the actual results to something different than what they actually are.

Q. Would you agree that, if there is a potential for financial bias, that it should be disclosed in the published article for that trial?

MS. WAHRENBERGER: Objection to the form of the question. You can answer.

THE WITNESS: I think that the need to disclose any financial relationship is set out by that -- the individual journal or publication regarding the requirements for publishing in that particular journal, and those need to be adhered to.

BY MR. GRAND:

Q. Okay. Independent of whether the journal has any rules regarding that, do you think that a researcher should disclose any potential conflicts of interest in an article that they are publishing?

MS. WAHRENBERGER: Objection to the form of the question. You can answer.

THE WITNESS: I think that the approach to

that in the medical literature has changed significantly over the last two decades or so. A decade or two ago the issues of financial disclosure was typically not something that was done and/or stressed. I think, as the last years have gone by, that there has been more focus on ensuring that researchers or even speakers list any financial relationship that they have with a company.

BY MR. GRAND:

Q. In forming your opinions about the risks and benefits of the TVT Retropubic did you review and consider Ethicon -- the testimony of Ethicon employees?

A. I did not consider the testimony of the Ethicon employees.

Q. Why not?

A. Because my decision regarding the clinical risks and benefits for any particular device or product that I use is based on the information provided in the peer-reviewed scientific literature and not based on company documents.

Q. Do you think Ethicon has a greater knowledge base about the risks and benefits of the TVT higher than you?

A. Than me per se? Possibly.

Q. Do you think Ethicon would have had relevant information to the risks and benefits of the TVT Retropubic that you did not have access to?

MS. WAHRENBERGER: Are we talking a specific time frame?

THE WITNESS: Yeah, I'm -- I'm not -- can you rephrase that question? I'm sorry.

BY MR. GRAND:

Q. Doctor, you would agree that Ethicon has greater access to information about the TVT Retropubic than you do, correct?

MS. WAHRENBERGER: Objection to the form of the question.

THE WITNESS: I think that that is probably true for any device that any physician uses in any field when they are operating versus the company itself.

BY MR. GRAND:

Q. Okay. So information, internal information, that Ethicon had relating to the TVT Retropubic would be relevant to your evaluation, wouldn't it?

MS. WAHRENBERGER: Objection to the form of the question.

THE WITNESS: I would have to see that --

that information to determine whether I think it is relevant or not.

BY MR. GRAND:

Q. Did you ask to see any internal Ethicon information relating to the TVT Retropubic?

A. I don't recall that I asked specifically for those documents, as, again, I'm making a decision and my expertise in the clinical use and the clinical risk/benefit profile of the particular surgery and device.

Q. So the testimony of Ethicon employees on this issue is not important to you, correct?

MS. WAHRENBERGER: Objection to the form of the question.

THE WITNESS: I think that the information provided in the peer-reviewed literature regarding the risks and benefits of what has been documented by multiple different investigators, multiple different sites over multiple different time periods and research projects are more important. Those are what I'm -- more important than what would per se be from Ethicon employee testimony, and that's the decision -- or that's the information I would use to make my decision as a clinician.

BY MR. GRAND:

Q. Okay. You don't actually know whether it's more important because you didn't review Ethicon testimony, correct?

A. I think that it would be very unlikely that there would be anything within the Ethicon testimony that would alter my decision-making regarding the risks and benefits of this particular procedure.

Q. And is the same true of internal Ethicon documents?

A. Yes.

Q. Doctor, in your report you've referenced the term "Gold Standard," correct?

A. Yes.

Q. Okay. That's not a medical term, correct?

A. Actually it's a term used quite frequently in the medical community.

Q. Do you know the origin of that term?

A. No, not specifically.

Q. Okay. Can you think of medical procedures that were once considered the gold standard that are no longer considered the gold standard today?

A. Yes.

Q. There are several, correct?

A. Yes.

Q. Doctor, we've marked as Exhibit 4 to your

deposition a document entitled "Updated Exhibit B to the General TVT Report."

(Exhibit 4 was marked for identification.)

BY MR. GRAND:

Q. Do you recognize this document?

A. No.

Q. You've never seen this document before?

A. No.

Q. Can you turn to the inside page, I guess the second page? I don't know if yours -- mine is double-sided. Do you see it says "Nicolette Horbach Reliance List"? Do you see that?

A. Yes.

Q. You've never seen this document before?

A. Not in and of itself, no.

Q. You can set it aside. Thank you.

Doctor, you drafted your own report, correct?

A. Yes.

Q. Okay. And is it fair to say that if I want to -- if I wanted to know the materials you relied upon in formulating your opinions, that they would be contained within the body of your expert report?

A. Most likely, yes. I think, yes, most likely. I mean, there is a lot of other material obviously over -- because of my training, education,

what I see on a day-to-day basis that I used in generating my report that isn't necessarily specifically referenced in that area in the report.

Q. Okay. I think I understand what you're saying. Other than your own experience and education, is there anything you've relied upon in formulating your opinions other than the documents cited in the body of your report?

MS. WAHRENBERGER: Objection to the form of the question.

THE WITNESS: Yes. The studies and documents specifically cited in the report were cited to refer to, let's say, specific statistics or numbers that I was quoting in the report. There are other studies that I have read over the years and/or more recently that helps to frame my perspective that I may not have specifically cited that particular statistic in my report and reference that particular article.

Some of that may be listed in this gigantic list here of reliance issues (indicating), and there were some additional references that I -- or a list of references that I had printed up last night that involved things that even I had pulled up in the last week or so as I was reviewing -- or maybe two weeks or so.

Q. Okay. Doctor, do you understand one of the purposes of a deposition is that I need to understand what your opinions are and what you've relied upon in formulating those opinions? Do you understand that?

A. Yes, I do.

Q. Okay. Now you've just told me that Exhibit 4, which purports to be your reliance list for your expert report, you've never seen before, correct?

A. I said that I've never seen it compiled in such a fashion, that whole compilation in such a fashion. I have not seen this specific printout, no. That doesn't mean --

Q. Okay. If I want to know -- I don't mean to interrupt you, doctor. Are you done?

A. Yes.

Q. Okay. If I want to know what you've relied upon in formulating your opinions, where am I going to find that material?

A. Either in this (indicating) --

MS. WAHRENBERGER: Referring to Exhibit 4.

THE WITNESS: Sorry, Exhibit 4, in the report itself, or in the list of additional references, which may be duplicate. Actually there may be some overlap that I have here, that I brought with me today.

BY MR. GRAND:

Q. Okay. Is that -- has that list been produced on the thumb drive?

MS. WAHRENBERGER: No, it has not. It was brought today by Dr. Horbach to this deposition.

MR. GRAND: Okay. I would ask counsel if you could make a copy of that list for me and email it to me?

MS. WAHRENBERGER: Sure.

THE WITNESS: Alternatively, I can, yeah, email it to -- I can just email the list to them and they can forward it to you.

MS. WAHRENBERGER: Do you want it right now?

MR. GRAND: Yes. We can do it during a break perhaps.

MS. WAHRENBERGER: Okay. During the lunch break, yeah.

THE WITNESS: Yeah, if I can just -- if I can get on the Internet, I'll email it wherever you want.

BY MR. GRAND:

Q. I would rather have a copy of the list you've brought with you.

A. Sure. We can fax it.

MS. WAHRENBERGER: Yeah.

BY MR. GRAND:

Q. Now, doctor --

MS. WAHRENBERGER: Jeff, give me your fax number, and we'll see if we can get the law firm to fax it when we take a break.

MR. GRAND: It's 212-584-0799.

MS. WAHRENBERGER: Okie-doke.

MR. GRAND: Thank you. I appreciate it.

BY MR. GRAND:

Q. Doctor, if you could -- I'm referring to Exhibit 4. If you look through this list, would you agree with me that a large number of the materials on this list relate to the Prolift product and not the TVT?

A. I would have to start looking through it here to be able to answer that for you.

Q. I apologize, doctor. The document is not paginated in any way, so it's difficult for me to point you to a specific page.

A. Since it's done alphabetically, you could ask me to look alphabetically. I mean, I see that there are references here for prolapse as well as for urinary incontinence.

It is my understanding that this list involves

all of the documents that have been forwarded to me at one time or the other from the defense attorneys.

Q. Okay. And that would be going back as far as 2012, correct?

A. It is -- that's potentially the case, yes. I mean, I don't know what specific criteria they chose versus just the entire list of everything. Some of this I have read, not read, as I felt appropriate.

Q. Okay. And is it fair to say that -- well, let's sort of break this down into categories. The first part of the list contains medical literature, correct?

A. That it appears, yes, correct.

Q. And to make it easier for you, if you look at the heading underneath your name, as you go through the list, it shows the category of document. Do you see that?

MS. WAHRENBERGER: Referring to up here.

BY MR. GRAND:

Q. Most of the list is comprised of medical literature.

A. Okay. Yes. Thank you.

Q. Okay? Now, with respect to the medical literature, did you collect this medical literature yourself?

A. This is a list of medical literature that was forwarded to me, as I mentioned, from the defense attorneys. Some of these would duplicate articles that I have pulled myself in my own independent research.

Q. Okay. So with respect to the TVT product, the TVT Retropubic, how did you identify medical literature?

MS. WAHRENBERGER: Objection to the form of the question.

MR. GRAND: Excuse me. I'll rephrase it.

BY MR. GRAND:

Q. With respect to the TVT Retropubic, how did you identify medical literature relevant to your opinions in this case?

A. That is -- there's a lot of -- that's a long process. I have reviewed or identified medical literature based on several different ways or techniques. One is based on studies that I know have been published in the literature because I've read them, you know, previously over the years as they have come out, some of which were obviously sentinel studies.

Some of the literature that I pulled was based on specific references made in certain articles to

further data or other discussions that might be similar to the article that I've just reviewed. Some of the information I pulled that I use based on a fairly extensive review that I did of the topic and the literature in preparation for taking my subspecialty board certification.

Some of it is based on going back and pulling articles that the plaintiff's expert has referenced, to go over those articles and any other articles perhaps cited in that as support. Some of it is involving a lot of time at the computer on PubMed researching based on specific topics, whether it was complications, issues related to reoperation for midurethral slings versus other surgeries, searching out mesh, mesh risk issues, you know, degradation issues, the carcinogen issues, and searching those on PubMed, searching by specific potential complications, whether it's hematoma, dyspareunia, searching based on chronic pain conditions in postoperative patients, searching based on hernias, hernia meshes and some of that literature.

I think there's obviously more that I'm -- but, yeah, it's a fairly extensive amount of time in the library.

Q. You testified earlier that you spent

approximately 60 hours preparing your general report. How much of that time was devoted to research? How much time was devoted to identifying and reading medical literature?

A. Probably at least two-thirds or so. I had also, as I said, I just sat for my boards not too long before that, so I had a fairly extensive collection of literature already that I had accumulated and pulled for that. So sometimes it was re-reviewing articles and data rather than having to pull new articles and data.

Q. And the medical literature that you actually discuss in the body of your report, did you read all those articles carefully?

A. Yes, I believe I read them carefully.

Q. Do you believe you summarized them fairly and accurately in your report?

A. Yes, I believe I did.

Q. And if the medical literature conflicts with your opinions in this case, you would want to see it, correct?

A. I think that I have -- I have still reviewed medical literature that does conflict in my opinion -- I have reviewed medical literature that states an opinion different than perhaps I have, yes,

I have reviewed that.

Q. And to the extent that there is literature out there that conflicts with your opinion, you would want to see it, correct?

A. Yes, I would want to see it. I think I certainly have seen it, yes.

Q. Okay. Do you consider yourself to be an expert with regards to materials science or on the mesh material that's used in the TVT Retropubic?

A. I consider myself an expert in terms of its clinical use as an implanting physician and the subsequent manifestation in the patients clinically, yes.

Q. So you're saying you hold yourself out to be a materials science expert?

MS. WAHRENBERGER: Objection.

THE WITNESS: That's not what I said. I said --

BY MR. GRAND:

Q. No, I'm trying to understand what you said. I asked you if you hold yourself out to be a materials science expert.

MS. WAHRENBERGER: And she responded.

BY MR. GRAND:

Q. Okay. You can answer the question.

A. I hold myself as a clinical expert in using a material in mesh within a clinical setting, not in the, necessarily, the biochemistry, shall we say, of materials.

Q. Okay. Thank you. In your report you discuss a number of professional society papers and opinions, correct?

A. Yes, I do.

Q. Did you read the references cited in those papers?

MS. WAHRENBERGER: Objection to the form of the question.

THE WITNESS: Can you be more specific? Did I look --

BY MR. GRAND:

Q. Well, many -- let me ask you a different question. Make it a little bit easier.

The society papers you discuss in your report, they contain references to various studies, do they not?

A. Yes, they do.

Q. Did you read the studies that were cited in those reports, in the professional society papers?

MS. WAHRENBERGER: Objection to the form of the question.

THE WITNESS: I believe that I have read the bulk of them. There might be one that I couldn't get access to, you know, in our medical library. There are certain journals that are difficult for us to get the full article, access to, but I think that the bulk of them I probably did, yes.

BY MR. GRAND:

Q. Okay. Did you satisfy yourself that the references in the society papers were actually supported -- that the references cited in the society papers actually support the statements contained in the society papers?

A. I think -- I can't answer that without you asking me specifically what statement and what reference.

Q. I'm not asking you about a specific statement or reference. I'm asking you about your process. You've cited a number of professional society papers in your report, correct?

A. Yes.

Q. Okay. Those papers contain references to studies, correct?

A. Yes.

Q. Did you review the underlying studies that are cited in those papers?

MS. WAHRENBERGER: Asked and answered.

THE WITNESS: As I said, I believe that I read the bulk of them, yes.

BY MR. GRAND:

Q. Okay. Is de novo urge incontinence a risk associated with the TVT Retropubic?

A. Yes.

Q. Is worsening urge incontinence a risk associated with the TVT Retropubic?

A. Yes.

Q. In your view what causes a mesh exposure?

A. I think that there are multiple factors that are associated with a mesh exposure. Do you want me -- I assume you want me to -- okay.

Q. Yes, please. Thank you.

A. Sorry. I think that there is -- there are issues that are patient-centered or patient-related, I think there are issues that are surgeon-related, and I think that there are issues that are material-related.

Q. Okay. Let's start with the issues that are patient-related. Could you describe those for me, please?

A. The -- there are aspects of a patient's either medical history, medical condition or tissues, surgical history, that will affect the quality of the

tissue in the vaginal area where we are operating. Those have been shown in the medical literature and can include issues related to a history of smoking, a history of diabetes. Obesity has been shown in some, not shown in other aspects of a risk factor. Age has been shown to be a risk factor. Prior surgery, prior, let's say, incontinence or prolapse surgery in the area. Vaginal atrophy, I guess the quality of the tissue has been shown. I don't remember if I already said smoking.

MS. WAHRENBERGER: You did.

THE WITNESS: Okay. Use of medications that might affect tissue healing, such as steroid medications, may also factor -- be a patient-related factor for mesh exposure.

BY MR. GRAND:

Q. And what about surgeon-related? I'm sorry. Were you done or are there other factors?

A. There probably are other factors that are patient-related that will pop into my head in a minute or two, but those are the ones that are, you know, most commonly the ones that I think about.

Q. Okay. And what about surgeon-related?

A. Clearly, during surgery the skill and expertise of the surgeon in being able to

appropriately dissect in the correct tissue plane is important; the ability to correctly pass the instruments or the trocars and to place the material in the correct tissue spaces that it's designed to be placed; the ability of the surgeon to correctly close the incision are going to be factors affecting mesh exposure.

There are factors that can happen intraoperatively that are not always per se surgeon skill set. That's sort of one of those things that sort of happens, such as, you know, exit bleeding, hematoma formation, infected incision line -- what else? -- if the surgeon has had an unrecognized, let's say, vaginal perforation at the time of the implantation of the device. Those are factors that can affect the likelihood of an exposure or not. I think that's mainly the surgical-related factors.

Q. And what would be the material-related factors?

A. The material-related -- actually I can go back for the, I guess, the surgeon-related factors. You know, again, ensuring how much of the mesh material comes in contact with the vaginal epithelium so that obviously more surface area coming in contact with the more superficial tissue in the vaginal

epithelium will put a larger area to be at risk for erosion.

MS. WAHRENBERGER: And just so it's clear, that was going back to surgeon-related --

THE WITNESS: Yes.

MS. WAHRENBERGER: -- issues.

THE WITNESS: Yes.

BY MR. GRAND:

Q. Yeah, that was clear. Thank you.

A. Okay. Sorry. Everything sort of -- sometimes it pops in, something different.

So relative to materials-related, it is going to be, again, the volume of material that is -- maybe not volume -- probably more even the surface area of material that is coming in contact with the vaginal epithelium, if we're talking specifically about vaginal exposures. It's going to depend upon -- there is some difference between types of meshes regarding the porosity of the mesh that -- the macroporous, you know, type 1 meshes will be typically less likely to be -- have erosions than the microporous essentially, like a polytetrafluoroethylene type mesh, that has a higher rate of exposure.

Again, we've talked just vaginal exposure, correct?

Q. Yes.

A. That's what you want? Okay.

Q. Yes. Do you have an opinion as to whether the foreign-body reaction caused by the implanting of a mesh, such as the TVT-R, Retropubic, is a transient reaction or a chronic reaction?

MS. WAHRENBERGER: Object to the form of the question.

THE WITNESS: I think that -- sorry. Can you repeat that? My brain just went someplace. It's getting hypoglycemic.

MS. WAHRENBERGER: I was going to say --

MR. GRAND: Do you want to break? We can break.

MS. WAHRENBERGER: It's between 25 and 20 of. Shall we plan to break around 1:00? I don't want Dr. Horbach to go too long without having something to eat.

MR. GRAND: I suggest we break now.

MS. WAHRENBERGER: Well, we have a question pending. Do you want to withdraw the question at this point?

MR. GRAND: I'll withdraw the question and we can pick up after lunch. I don't want the --

MS. WAHRENBERGER: Okay. So can we resume

at 1:00 or do you need more time?

Do you think you need more time?

THE WITNESS: No, I'm fine. We just got to find someplace that is going to be --

MS. WAHRENBERGER: No, I think they are bringing food in.

MR. GRAND: I have 20 to 1:00 now. Is 20 minutes enough time for you?

MS. WAHRENBERGER: What do you think? Yeah. Is that okay with you?

THE WITNESS: Yes. We would all like to be able to finish and go about our Christmas shopping or return things or something, so I'm fine to make it a short lunch.

MR. GRAND: That's fine.

MS. WAHRENBERGER: 1:00.

MR. GRAND: We'll plan on returning at 1:00.

VIDEO SPECIALIST: The time now is 12:38. We're going off the record.

(Proceedings recessed.)

VIDEO SPECIALIST: The time now is 1:04. We are back on the record.

BY MR. GRAND:

Q. Doctor, during the break I was faxed a copy

of the document you referenced before concerning additional references.

A. As I said, I'm not totally sure that these are additional or not duplicated here, but as I -- some of these were things that I pulled up myself as I was researching. I just kept a running list to make sure that there wasn't something that was missing.

MR. GRAND: Okay. Can we go ahead and mark this as Exhibit 5 to the deposition?

(Exhibit 5 was marked for identification.)

BY MR. GRAND:

Q. Doctor, when did you compile this list?

A. It's been over the last couple weeks as I was researching for my supplemental report and, you know, depo prepping, et cetera.

Q. Okay. Looking at this list, it seems as if the majority of references deal with sexual function after surgery for stress urinary incontinence. Would that be fair?

A. That's a good question. There are a number of those -- a number of the articles that are looking at that, yes. That was one of the things that I was researching regarding sexual function after any stress incontinent surgery and/or midurethral slings and/or following any erosion issues.

Q. And there are also articles on here relating to urge incontinency, correct?

A. Yes, I believe so. Yes.

Q. And there's articles in here relating to infection, correct?

A. Yes, I believe so.

Q. Okay. Is there a reason you were focusing on these issues in the last two weeks?

A. I was focusing on these issues relative to potential complications associated with sling surgeries in relation to having reread Dr. Rosenzweig's depos and some of the comments that he made.

Q. Okay. Are you aware that these are the types of injuries that are alleged by the plaintiff in this case?

A. I understand that there are a couple different issues that she has raised, yes. And I read his expert report, so -- specifically on the patient.

Q. Okay. Have you been asked by defense counsel to tell your opinions to address case-specific issues for Mrs. Corbet?

A. Not for case-specific issues regarding her care but more for global issues of the TVT or midurethral slings, TVTs impact on potentially sexual

function or overactive bladders or pain issues, et cetera, afterwards.

Q. Okay. And all of the articles on this list were available at the time you wrote your general report, correct?

A. My original general report?

Q. Yes.

A. My first one? Not all of them, no. Some of them have been published subsequent to the time -- I mean there's one here I see from 2015. Some of them, yeah, there certainly could be some of them -- there's another 2015 --

Q. Other --

A. -- 2014.

Q. Well, you wrote your report in 2014, correct?

A. Correct, but midway through the year. So some of the -- some articles for 2014 came out subsequent to -- some articles for 2014 came out subsequent to my report, and both of Dr. Rosenzweig's depositions came out subsequent to my report.

Q. Okay. Were you sent these articles by defense counsel?

A. These articles? No, these are articles that I specifically pulled when you were asking me

about my, you know, my whole process of how do I research this and go into the library, et cetera.

Q. Okay. So you pulled these articles yourself over the last two weeks?

A. Yes.

Q. Okay. Thank you. You can set that aside.

Doctor, would you agree that implantation of a synthetic mesh such as contained in the TVT Retropubic causes a foreign-body reaction in the patient, correct?

A. Yes.

Q. Okay. Do you have an opinion as to whether that foreign-body reaction is a transient reaction?

A. I think that the foreign-body reaction is somewhat more pronounced usually in the beginning acutely. That more pronounced effect is more transient, and, assuming that the patient does not experience an erosion, then I think that the foreign-body reaction does continue but not at the same -- not at the same intensity and/or, you know, manifesting as potentially clinically relevant, if that makes sense.

Q. And what do you base that opinion on?

A. Which part of the opinion?

Q. That the foreign-body reaction diminishes

over time. Is that what you stated?

MS. WAHRENBERGER: Well, no, she said it was less intense and of less clinical relevance.

THE WITNESS: No, my comments were that over time in a patient that does not experience an erosion, that the foreign-body reaction will continue, but that it may not manifest itself in a clinically relevant way.

BY MR. GRAND:

Q. Okay. So is the foreign-body reaction chronic?

A. That's the definition of a foreign-body reaction. The body has a response to it as long as it's there, whether it's a suture or a mesh or a screw or a hip implant, like I just had, or any of those things.

Q. Doctor, you're aware that Ethicon discontinued the sale of certain pelvic organ prolapse and SUI repair products, correct?

A. Yes, I'm aware of that.

Q. Do you have any understanding as to why those products were discontinued?

A. I have -- I heard explanations regarding it, but I don't know how accurate those comments were or not.

Q. You don't intend to offer any opinions on that at trial, correct?

A. About why they discontinued the use?

Q. Yes.

A. I don't believe so unless I'm specifically asked by, you know, you or counsel. I mean, I'm not -- I'm not -- I'm not proactively going forward in asking those opinions. The hard part is when you ask if I'm ever going to state an opinion about this, I don't know what questions necessarily I'm going to be asked, but I'm not proactively going forward as that as being one of my stated opinions. Does that make sense? Hopefully.

Q. It does. You haven't reviewed documents relating to the discontinuation of the POP products or the SUI products, have you?

A. Ethicon documents? No, I have not.

Q. Okay. Have you reviewed any testimony relating to that?

A. No, I have not.

Q. So at this time do you have any opinions relating as to why Ethicon decided to discontinue certain POP and SUI products?

A. I don't have opinions. I've, you know, as I said, I've heard reasons or rationales, but I'm not

sure that I have an opinion specifically about that.

Q. Okay. Where did you hear those reasons and rationales?

MS. WAHRENBERGER: If I could short-circuit this, I don't think there is any anticipation that Dr. Horbach will be asked questions about her opinion as to why Ethicon discontinued any products at the Corbet trial.

MR. GRAND: Okay. Thank you.

THE WITNESS: Okay. I don't have to answer it.

BY MR. GRAND:

Q. Do you consider yourself an expert with respect to the design elements of the TVT Retropubic?

MS. WAHRENBERGER: Objection to the form of the question.

THE WITNESS: Yeah, I'm not sure what you mean about the "design elements."

BY MR. GRAND:

Q. Okay. Let me give you examples. Do you have opinions as to whether the TVT Retropubic is a lightweight or heavyweight mesh?

A. I think that, relative to some of the meshes that we've used previously in the past, it has determined to be definitely lightweight. Some other

people will classify it more as heavyweight. The definition of what's lightweight and what's heavyweight has evolved and/or there's different classifications depending on who you read. So I typically would put it into more of a lightweight type of category.

Q. Okay. Do you have any opinions relating to the differences between mechanical-cut and laser-cut TVT Retropubic mesh?

A. In my experience -- excuse me. In my experience clinically I don't see a difference in how the two meshes behave either during implantation or subsequent to implantation in the patient.

Q. How many laser-cut TVT Retropubic meshes have you implanted?

A. I can't recall specifically. I mean, I know I've certainly implanted laser-cut Ethicon midurethral slings, because that's what the Exact is, but I don't remember in the specific Retropubic whether I was using primarily -- I mean, obviously primarily machine-cut in the beginning, but I don't recall how many I have done in that transition time period when it became an option of laser-cut versus mechanical-cut.

Q. Do you recall when the TVT Retropubic

became available in laser-cut?

A. I think it was around 2006, but you had to specifically order it as laser-cut versus mechanical-cut, and I don't recall at this point now whether our hospital ordered it specifically one way or the other.

Q. So sitting here today you don't know whether you've ever implanted a TVT laser-cut mesh, correct?

MS. WAHRENBERGER: Objection.

BY MR. GRAND:

Q. For Retropubic.

A. Well, I mean, the Exact is a Retropubic TVT, a retropubic midurethral sling.

Q. Okay. I'm not asking --

A. It's just a different handle -- I'm sorry.

Q. I'm not asking you about the TVT Exact, doctor. I'm asking you about the TVT Retropubic laser-cut.

A. I cannot tell you one way or the other whether or not I've done a laser-cut one versus mechanical-cut only.

Q. Did you review any internal documents relating to this issue, Ethicon internal documents?

A. Regarding to the issue of what?

Q. Laser-cut versus mechanical-cut.

A. I did review some Ethicon internal document emails regarding the discussion of should they offer laser-cut in addition to mechanical-cut for the traditional TVT Retropubic.

Q. Did you view -- did you review any laser-cut internal studies or testing regarding mechanical-cut versus the laser-cut mesh?

MS. WAHRENBERGER: From Ethicon?

MR. GRAND: I said Ethicon.

THE WITNESS: I think that I did perhaps in the prior, you know, in formulating the original general report, you know, a year and a half ago. I seem to recall I did not re-review that specifically in the last short period of time, but I think I recall seeing some of that, yes, but I still can't give you the details.

BY MR. GRAND:

Q. Doctor, would you agree with me that a known complication of the TVT mesh is chronic pain?

A. Yes.

Q. Would you agree with me that one of the risks of the TVT Retropubic is pain with intercourse which in some patients may not resolve?

A. I think that that is a very -- I think

that's a very uncommon risk, at least in my experience with the retropubic procedure.

Q. Okay. I'm not asking you whether it's common or uncommon, doctor. I'm asking if you would agree that one of the risks of the TVT Retropubic is pain with intercourse, which in some patients may not resolve?

A. I have seen that reported in the literature, yes.

Q. Would you agree with me that one of the risks of the TVT Retropubic is contraction or shrinkage of the tissue in combination with the mesh?

A. I have seen that reported in studies where they have interpreted that there was contracture based on either the size of explanted mesh materials or I think even based on perhaps ultrasound measurements, if I recall.

So I think they have made the -- they have made the clinical assumption that this was -- that contracture was occurring based on changes or other parameters that they noticed.

Q. Is that a yes, that you would agree it's a known risk?

A. Yeah, I guess with any -- yeah, I suppose I would say, yes, that that's a known risk.

Q. Would you agree with me that one of the risks of the TVT Retropubic is that, when an adverse reaction occurs, further surgery may be required to correct it?

A. Yes.

Q. Would you agree with me that one of the risks of the TVT Retropubic is that, when an adverse reaction occurs, one or more revision surgeries may be necessary to treat it?

A. Yes.

Q. Would you agree that one of the risks of the TVT Retropubic is that, when revision surgery is required, significant dissection of tissue may be needed?

A. I'm not sure what you mean by "significant dissection." Yes, you have to dissect. I'm not sure whether, you know, you call it significant dissection or not.

Q. Okay. Would you agree that one of the risks associated with the TVT Retropubic is scar plating and bridging fibrosis?

A. I've not seen that clinically, although I have seen pathologists report that on explanted -- excuse me -- on explanted specimens that have been evaluated histologically.

Q. Okay. So would you agree that's one of the risks, then?

A. Yes, I would suppose so. I mean, I haven't seen it clinically, but I've seen it reported.

Q. Would you agree that scar plating and bridging fibrosis can cause contraction?

MS. WAHRENBERGER: Objection to the form of the question.

THE WITNESS: I think -- are we talking contraction of the mesh or the whole sort of tissue-mesh complex or ...

BY MR. GRAND:

Q. Yeah, let's say the tissue-mesh complex to be fair.

A. I think, again, there have been authors who have stated that their findings suggest that. I'm not always sure -- I'm not sure that I agree that that, again, clinically is an issue and/or that they necessarily come to the correct conclusion based on what they're -- what they're seeing in their research.

Q. Would you agree that scar plating and bridging fibrosis can cause pain in a patient?

A. I think that pain can be found in patients where that type of histologic sample, I guess, has been seen. I'm not sure that you can say that the

pain is caused by that.

Q. Would you agree that scar plating and bridging fibrosis -- can cause erosion?

A. I think -- could it ever possibly? It's perhaps possible. I don't think that that typically, though, is what you're going to see with, you know, scar tissue or tissue growing into the mesh. I don't think that typically erosion is going to be the more way you see that.

Q. Do you agree that scar plating and bridging fibrosis can lead to extrusion?

A. I think if just scar plating is there and that's the only abnormality and there's nothing that is abnormal on the surface epithelium, I don't think that the scar plating in itself by itself in a normal type of epithelium without a prior perforation is going to per se cause an extrusion.

Q. Have you ever studied whether the Prolene mesh in the TVT Retropubic can degrade?

A. I have studied it in, you know, in clinical situations in patients where I have operated on and -- or reoperated on and/or followed over time in terms of changes in their anatomy from any degradation.

Q. Have you ever seen degradation in any mesh explants under a microscope?

A. Have I seen it under the microscope? No.

Q. Do you know whether the microscope you were using was sufficiently powered to see degradation?

A. Probably not since I think most of the degradation reports seem to be more with, you know, scanning electron microscopy or other very specialized type of equipment and/or preparations.

Q. Have you read literature relating to this issue?

A. Yes, I have.

Q. Have you read internal Ethicon documents relating to this issue?

A. I don't recall that I have. I don't remember anything in particular, no.

Q. Have you read any testimony of Ethicon employees relating to this issue?

A. No.

Q. Just give me a second, doctor. I want to ask you about some things that are in your report specifically but some of which I think I've already covered. So just give me a moment to catch up.

Doctor, if you can look at the exhibit, what's been marked as Exhibit 2, your general report, and turn to page 26, please.

A. Okay.

Q. Okay. Do you see under the heading of Complications of MUS versus Other Surgeries for Stress Incontinence?

A. Yes.

Q. Okay. If you look at the third sentence of that paragraph, it says:

Many of the earlier studies published on the outcomes of Burch colposuspension and pubovaginal sling procedures did not specifically describe all complications, failed to even consider quality of life and sexual function parameters and often had rather short length of follow-up?

Do you see that?

A. Yes.

Q. Okay. That criticism would be true of many of the TVT studies as well, correct?

MS. WAHRENBERGER: Objection to the form of the question.

THE WITNESS: Actually the quality of the majority of the TVT studies are much better than what I've listed here of the original Burch studies. They do address complications much more comprehensively than prior reports had done as well -- from the

complications.

Follow-up of the -- many of the TVT studies now are longer than just the one-year follow-up in patients, and especially some of the TVT studies that are done like through the NIH protocol and the Tomas study, they do indeed specifically address sexual function and quality of life issues.

BY MR. GRAND:

Q. Okay. Doctor, just to be clear, I wasn't asking you about recent studies. I was asking you about the earlier studies. Isn't it true that most of the early studies on the TVT were short-term studies?

A. I think that the original report was closer to two years' follow-up, if I recall. I'd have to look back at it. It did talk about complications. It did not address sexual function or quality of life issues in the initial report.

Q. Isn't it true, doctor, that very few of the TVT studies actually collected information on sexual function such as dyspareunia?

MS. WAHRENBERGER: Objection to the form of the question. Go ahead.

THE WITNESS: During which period of time are we talking about?

BY MR. GRAND:

Q. All periods of time. Strike that.

Do you have an understanding as to how many of the TVT studies you reviewed actually collected data on dyspareunia?

A. Dyspareunia or pain with sex is one of the domains of the sexual function questionnaire that is now commonly employed in doing the prospective studies for stress urinary incontinence treatments, including the midurethral slings.

So there's a domain part of that that talks about pain with intercourse, and that's part of the -- I think there's five different domains that are looked at. So, yes, pain with intercourse is part of the sexual function questionnaire.

Q. And that's a more recent development, isn't it?

A. I can't tell you when the first questionnaire was used in a TVT trial for this. I mean, the Tomas trial was going on five, probably eight years ago or so, and that certainly included it.

Q. Could you turn to page 30 of your report, doctor?

A. Yes.

Q. And if you see the heading there, IFU in Professional Education Opportunities? Do you see

that?

A. Yes.

Q. If you look, I guess, the second sentence above that, my experience has confirmed that a minimally invasive MUS is a preferred option for treating stress incontinence. Do you see that?

A. Yes, I do.

Q. Okay. You say, "It is the Gold Standard --" and before I read on, I want to actually confirm what you're talking about. Are you saying that midurethral slings generally are the gold standard or are you saying that the TVT is the gold standard?

A. In this particular situation I think I am saying that minimally invasive slings are the gold standard.

Q. Okay. And you go on to say, and I agree with the position statements, practice guidelines and analyses by AUGS, AUA, SUFU, SGS, ICS, NICE and IUGA, which recognize TVT as a first-line option for women.

Did you mean to say MUS there or are you saying that those societies are recommending the TVT Retropubic as the first-line option for women?

MS. WAHRENBERGER: Objection. Retropubic isn't even there.

BY MR. GRAND:

Q. Doctor, you can answer the question.

A. The -- I think the reference would be more for midurethral slings as first-line option.

Q. Okay. So you aren't suggesting there that those societies are saying that the TVT is the first-line option, correct?

A. The Ethicon TVT, no, I'm not saying that that -- I'm saying midurethral slings.

Q. Okay. Thank you. With respect to professional education, did you review professional education materials that were created by Ethicon for the TVT Retropubic?

A. Yes, I did. I reviewed some of the -- I reviewed lecture slide sets that were developed as part of the professional education material.

Q. Okay. And did you -- those materials typically made reference to various studies in support of the claims in the materials, correct?

A. I think I'd have to look back at the slide set to be able to answer that. I think they probably did, but I would -- I'm not totally sure. I've reviewed a lot --

Q. You didn't check --

A. No, I've reviewed a lot of material,

especially, you know, as getting in preparation for the deposition. So sometimes things get a little blurry about what you remember or what you don't remember. So prior to answering -- I know I looked at that, the professional education slides, but which studies they quoted or not, I would have to look back at the slides.

Q. Okay. Okay. Doctor, I'm going to ask the court reporter to mark as Exhibit 6 an email from Eric Globerman dated May 24, 2004.

(Exhibit 6 was marked for identification.)

BY MR. GRAND:

Q. For the record this document is Bates stamped ETHMESH 11840160.

Doctor, do you see it's an email from Eric Globerman to Cindy Pypcznski?

A. Yes, I see that.

Q. Do you recognize either of those names?

A. No.

Q. Okay. And do you see the subject line is RE: TVT Targets?

A. Yes.

Q. Okay. And I want to direct your attention to paragraph 1 of that email. Do you see it says, Fairfax Hospital?

A. Yes.

Q. Do you see it says, "Dr. Wellgoss and Horbach have both been using the Boston Scientific Advantage sling"? Did I read that correctly?

A. Yes, that's what it says.

Q. Okay. "Boston Scientific has consigned this product to the hospital and also discounted the price." Did I read that correctly?

A. Yes.

Q. Were you using the -- were you not using the TVT in May of 2004?

A. I don't know. I would expect that I was potentially using both of them. Sometimes the hospital has gone back and forth with Ethicon regarding contracts and getting, oh, a, whatever, discounted stuff whatever so that they could be able to have different products available. Sometimes there's a year that they're there; sometimes there may be a year that they are not.

Q. And the statement "Boston Scientific has consigned this product to the hospital and also discounted the price," would that suggest to you that the hospital was only carrying the Advantage as opposed to the TVT-R?

A. No, that would not suggest that to me, not

for -- not typically for Fairfax. They may have had the discounted for the Boston Scientific and been preferring that we use that, but we've gone back and forth with Fairfax for many years regarding what materials or not or what slings or what mesh for prolapse repairs we were going to end up being -- wanting to use.

Q. You can set that aside, doctor.

MR. GRAND: I'm going to ask the court reporter to mark as Exhibit 7 an email from Cindy Pypcznski dated February 9, 2009, subject line INOVA.

(Exhibit 7 was marked for identification.)

BY MR. GRAND:

Q. Doctor, what's INOVA?

A. INOVA is the parent company for my hospital and a number of other hospitals in the northern Virginia area.

Q. And do you see in the email there's several doctors listed? And do you see your name there?

A. I do.

Q. And you're there as using the Prolift, Apogee and the Perigee. Do you see that?

A. Correct.

Q. And those are products you were using for -- to repair pelvic organ prolapse?

A. No. It's incorrect.

Q. Incorrect? And do you see it says you were using Boston Scientific slings?

A. I see that it --

Q. Is that correct?

A. I see that it says that, but I'm saying that this information, wherever they got it, is incorrect. I have never used an Apogee or Perigee sling -- or for a prolapse procedure period. So whoever said I was using it --

Q. Okay.

MS. WAHRENBERGER: Let her finish.

THE WITNESS: So whoever said that I was using this, it's not accurate. So if they are saying that I am using things that I'm not using, then also saying I'm not using things that I am using, I think, is certainly conceivable. This simply is not accurate.

BY MR. GRAND:

Q. Okay. You were using the Prolift at the time, correct?

A. Yes, I was using Prolift.

Q. And you testified --

A. Actually --

Q. -- earlier --

A. Actually, yes, 2009, I think -- trying to remember whether that was around the time that we began not using Prolift or not. It was -- I don't even remember whether I was still using Prolift at that particular time.

Q. Okay. Do you have any reason to doubt you were using -- you were using Boston Scientific slings at that time and not the TVT-R?

A. I think that I was -- I'm pretty sure that I was using Boston Scientific at that time and probably not the TVT-R. That's the middle round, as I said to you, where I was going in transition.

Q. Understood. Thank you.

MR. GRAND: I'm going to ask the court reporter to mark as Exhibit 8 an email from Cindy Pypcznski dated December 14th, 2010.

(Exhibit 8 was marked for identification.)

MS. WAHRENBERGER: Just for the record, none of the documents that you've passed to us, Mr. Grand, have the Bates stamp marking on the bottom. It looks like the way they were photocopied --

MR. GRAND: That must be the way they were printed out because they were on the PDFs I sent.

MS. WAHRENBERGER: Yes. So I just wanted you to be aware that -- they're going to be attached,

I assume.

MR. GRAND: Understood. For the record I'm going to read them in, so if there's any dispute later you can confirm it.

MS. WAHRENBERGER: I can't confirm it one way or the other because there's no -- I can't see a Bates stamp.

MR. GRAND: I'm not asking you to confirm it right now. Okay? I'm going to represent to you what the Bates number is and --

MS. WAHRENBERGER: Fair enough. Go ahead.

MR. GRAND: Okay. I had already read the Bates number for Exhibit 6. For Exhibit 7 the Bates number is ETHMESH 11841786. For Exhibit 8, which we just handed to the witness, the Bates number is ETHMESH 11847771.

MS. WAHRENBERGER: And there are two additional pages after that.

MR. GRAND: Yes. Oh.

MS. WAHRENBERGER: The next two numbers, I assume?

MR. GRAND: It's sequential. The last Bates number is 11847773.

BY MR. GRAND:

Q. Dr. Horbach, do you see this email is from

Cindy Pypcznski to Carole Carter-Cleaver?

A. Yes, I see that.

Q. Okay. And do you see there's a number of names listed under the cc line?

A. I -- under the cc line, yeah, there are a lot of names. Okay.

Q. Yeah. Do you recognize any of those names?

MS. WAHRENBERGER: And we're talking about the KTrombly, Justin Preston, that group of names?

MR. GRAND: Yes.

MS. WAHRENBERGER: Okay.

THE WITNESS: Only that I think the Kyle Boyle was on the one just before that email. The previous email we looked at, Kyle Boyle was one of the people, but the other names I don't recognize.

BY MR. GRAND:

Q. Yeah. Doctor, to be clear, I don't expect that you would have ever seen any of these emails. I'm asking if in the course of your career and occasional interactions with Ethicon whether you recognize any of these names as people you've met or spoken with.

A. You know, Kyle, that name sounds familiar. He may have been the person that, you know, that was around the operating room and showing us the new

things, whether it's morcellators or whatchamacallit, you know, the ligature kind of things, et cetera, that we do. So I think, yeah, I think I've interacted with him previously.

Q. Okay. And that's Kyle Boyd?

A. Yes, I believe so.

Q. Okay. Do you see on the subject line is "Big East Division: TVT Roundtable"?

A. Yes.

Q. Do you see that?

A. Yes.

Q. Okay. And do you see you're listed -- you're listed on -- you're at the top of the list on this list of surgeons, correct?

A. My name is there. I don't know what that means.

Q. And do you see next to your name in parentheses it says "UroGyn uses BS Advantage"?

A. I see that, yes.

Q. Do you see that?

A. Yes.

Q. Okay. And you would know that to be the Boston Scientific Advantage sling?

A. I assume that that's what he means or she means.

Q. Okay. And that's the sling you were using in December 2010?

A. It was one of the slings. I mean, again, this document -- the name of my practice isn't even correct, so, you know, the accuracy of these emails going back and forth, again, I don't know what the emails are, but, you know, my practice wasn't at that point, you know, Northern Virginia Pelvic Surgery Associates. We had a totally different name to our practice, so -- anyway ...

Q. Were you are using the -- had you started using the TVT Exact at this point in time?

MS. WAHRENBERGER: That's December of 2010.

THE WITNESS: I don't remember, but around this time period I was also -- I had privileges at another hospital, and so I was operating there at times as well, and they actually in the beginning -- they only carried the Ethicon products, and so I think it would have been a TVT Exact when I was operating at the other hospital. So I think there was around that time period that I would have potentially been using one or both.

BY MR. GRAND:

Q. Okay. Thank you.

A. What is this roundtable thing? Can I --

I'm just -- I can't ask questions.

MS. WAHRENBERGER: No, no questions.

THE WITNESS: Sorry.

BY MR. GRAND:

Q. Doctor, I know you've used the -- strike that.

Doctor, I have to ask you another question. I am not -- I want to assure you that I am not trying to be disrespectful in any way or pry into your personal life in any way. I'm only asking this question because it was spoken about in an Ethicon document that was produced in this litigation. And I think it may relate to your opinions in this case.

A. Okay.

Q. What?

A. Okay. That's a good -- that's an interesting forwarding.

Q. I'm doing it, doctor, because I'm trying to assure you that I'm not trying to be disrespectful.

A. That's okay. Thank you.

MR. GRAND: I'm going to ask the court reporter to mark as Exhibit 9 an email from Jacqueline Russo dated January 9th, 2003.

(Exhibit 9 was marked for identification.)

THE WITNESS: Ah. Okay.

BY MR. GRAND:

Q. Okay. So you --

A. I was wondering --

Q. Do you see --

MS. WAHRENBERGER: Wait until he asks the question.

THE WITNESS: Sorry.

BY MR. GRAND:

Q. Do you see this is an email from Jacqueline Russo to Cheryl Bogardus and others?

A. Yes.

Q. Okay. And do you see the subject line is "SUI/TVT article in Working Mother Magazine"?

A. Yes.

Q. Okay. And if you look at the body of the email, they are discussing the article generally and that you're quoted in the article. Do you see that?

A. Yes, I do.

Q. Okay. I want to draw your attention to the -- to the last two sentences. It says, "An interesting note, Dr. Horbach discussed her personal experiences with stress incontinence that ultimately she was treated with surgery." Do you see that?

A. Yes, I do.

Q. Okay. So, doctor, I'm just asking this

because you are an expert in this case.

A. That's okay.

Q. Have you received the mesh implant for stress urinary incontinence?

A. I had my surgery done -- I had a sling in 1999, and I had severe intrinsic sphincter deficiency at that point, and TVTs weren't really being used at that point for severe ISD. The data just wasn't out at that point. So I had a traditional fascial sling. Nowadays I would have had a TVT.

Q. Doctor, do you intend to testify regarding your own personal experience with this surgery at trial?

A. With my personal experience with my sling surgery?

Q. Yes, your own condition, your own treatment.

A. I didn't necessarily intend to bring that up as part of it -- of the situation. I mean, it's -- I've been open and there has been something in a national magazine about the fact that I think women need to be able to be forward and talk about it, and if I'm not willing to step forward and say I've had it, then how can I expect them to say they have had it, but whether that is going to come up at trial, I -- we -- I've not been specifically asked to bring

that up at trial or discuss that at trial.

Q. Okay. Have you had complications as a result of your own surgery?

A. I mean, I've had, you know, after effects. It's not what I would call complication, but, you know, changes in how my bladder functions compared to perhaps preoperatively, but the trade-off for me, again, in the risk/benefit is much more in favor of having done it. I mean, I pee slower, so, you know, that's not that big of a deal to me.

Q. Okay. I guess my question was you haven't suffered any long-term -- you don't suffer any complications today as a result of your sling surgery, do you?

A. Again, it depends on what you -- this is that whole definition of what's a complication versus what is a change or a difference compared to what it was previously.

So just because something is different than what it was previously doesn't necessarily mean it's a complication. If you were to say using some definition my voiding would be considered to be perhaps, I guess, it's not the same as what it used to be, it doesn't really affect my life, but this is where that whole issue of is it a complication versus

is it a change in things.

Q. Okay.

A. Does that make --

Q. I think you meant -- I'm sorry. I thought I heard an echo.

A. No.

Q. I think you mentioned when I first asked you about this that, if you, I guess, had to do it all over again, you would use a TVT. Is that what you said?

MS. WAHRENBERGER: Objection, mischaracterization.

THE WITNESS: I said --

MR. GRAND: I'm not trying -- I'm asking her the question so I'm not mischaracterizing it. I'm asking her to clarify what she said.

THE WITNESS: If I were to undergo surgery for stress incontinence now in this day and age with the data that we have available, I would choose to do a TVT, yeah.

BY MR. GRAND:

Q. A TVT Exact?

A. Yeah, I would probably -- I mean, part of it is actually I would probably, trying to be a good patient and not being a doctor who is telling another

doctor what to do, I would probably give my surgeon the, you know, choice of, if you want, if it was my partner and he wanted to do it as the Retropubic TVT or my other partner wanted to do the Exact, fine, whichever one you prefer doing. I'm not going to tell one of them to use one versus the other.

Q. Okay. Thank you, doctor.

A. That's okay.

Q. I appreciate your candor. And, again, I was not trying to be disrespectful.

A. Actually this --

Q. I have no --

A. This is fine. I mean, I -- that doesn't bother me at all. I'm very open with my patients about it.

MR. GRAND: Doctor, I have no further questions for you.

MS. WAHRENBERGER: You know, we're going to take a quick break. I have a few questions, but we'll come back in a couple minutes.

MR. GRAND: Sure.

VIDEO SPECIALIST: The time now is 2:01. We are going off the record.

(Proceedings recessed.)

VIDEO SPECIALIST: The time now is 2:12.

We are back on the record. This is the beginning of disc 3.

EXAMINATION

BY MS. WAHRENBERGER:

Q. Dr. Horbach, I have some questions I'd like to ask you. You've been asked some questions by Mr. Grand about foreign-body reaction. Do you recall those questions?

A. Yes.

Q. Is foreign-body reaction something that is seen all the time every time when a foreign body is introduced into the human body?

A. Yes. Any foreign -- any nonhuman, non-that-person, essentially, material that is in an individual's body will create a foreign-body reaction, whether it's a splinter or a suture that is permanent or a mesh or a bone anchor or a screw or a joint replacement or a stent or anything like that.

Q. Does a foreign-body reaction differ from an inflammatory response?

A. An inflammatory response usually is a much more accelerated or much more intense type of body reaction than what you might see with a foreign-body reaction. So typically an inflammation will have a foreign-body reaction but not always would a

foreign-body reaction have evidence of, you know, clinically significant inflammation.

Q. What would be the signs and symptoms of clinically significant inflammation?

A. For -- in the vaginal area it will usually be a combination of a couple different symptoms. Number one, they will usually have some type of abnormal discharge. It will either be more yellow, more tan, grayish kind of discharge. It is -- it usually has a little bit of an odor to it as well. There will typically be -- there can be some periodic spotting or bleeding that the patient reports sometimes just during regular sort of physical activity, other times following sexual activity. There can be occasionally, depends on where the inflammation is, there could be some irritated symptoms, urinary type symptoms of irritation.

In examining the patient she's going to usually, in addition to having the discharge, she may show an area of the vagina with some increased erythema, redness. That area will typically be more delicate or what we call friable, so you barely touch it with a Q-tip and you'll see blood on the Q-tip or see spotting.

And sort of in the more final phase of it you

will actually see what we call frank granulation tissue, which looks like sort of a red, beefy, polyp-y looking tissue that is present around the area of inflammation.

Q. After a TVT Retropubic sling is implanted and the incision that allowed the implantation of it closed, where is the TVT sling located?

A. It is located under the vaginal epithelium or tissue layer under the mid portion of the urethra. So it is usually about a centimeter and a half or so inside from the hymen, under the epithelium and the skin, and then it tunnels on either side of the urethra up behind the pubic bone and out through the abdominal incision.

Q. Once it's in place is the sling within the vaginal cavity or outside of it?

A. It's deep to the vaginal cavity. It's not in the vaginal lumen or cavity itself. It's under the skin.

Q. When a foreign-body reaction or an inflammatory response occurs, can they be seen at histopathological analysis?

A. Yes.

Q. Is foreign-body reaction an inflammatory response part of the normal healing process in the

body?

A. A foreign-body reaction, yes, is part of the normal process of healing, when there's anything there that's not supposed -- or not normally there. You can often see inflammation in the early stages of healing. As the incision is healing, sometimes it will look a little red or even a little bit of granulation tissue present within the first, you know, few weeks or months, but usually as the healing completes that the inflammation changes will no longer be seen.

Q. Does scar tissue develop all the time after an incision has been made and closed as part of surgery?

A. Yes. I mean, that's one of the challenges of doing surgery that, whenever you make an incision and the tissue heals together, that area almost always is going to have -- be more restrictive and have less stretchability or pliability than the surrounding tissue that's separate from the incision.

Q. Does scarring occur even when a foreign body is introduced such as a sling?

A. Yes, with or without -- with or without a foreign body you're still going to have scar tissue form.

Q. Is the scar tissue that develops permanent within the body?

A. Yeah, that -- that scar tissue is going to be permanent. The body doesn't dissolve the scar tissue.

Q. The tissue reaction that occurs when a TVT mesh is implanted is considered to be part of what is desired as the -- as part of the introduction of the mesh into the body; isn't that true?

MR. GRAND: Objection.

THE WITNESS: Okay. Yes, part of what ideally helps a TVT do what it's supposed to do and hold the tissues in its proper location is the ingrowth of tissue through the mesh to create sort of an interaction of both mesh and tissue together, which is, as opposed to materials such as Gore-Tex, which were used as a sling for a period of time, where scar tissue didn't actually grow into the sling and that was found to be much less effective as a sling material.

BY MS. WAHRENBERGER:

Q. Does the tissue reaction which you've described occurs assist in making the sling effective in preventing any further stress incontinence?

MR. GRAND: Objection.

THE WITNESS: Yes, that -- that scar tissue is part and parcel of the overall effect of the sling in helping to correct the stress incontinence.

BY MS. WAHRENBERGER:

Q. When mesh is the cause of pain within a woman's vagina, in your experience is removal of the mesh curative of the pain that the patient reports?

A. It depends on what procedure, you know, has been done, you know, what type of procedure was done to implant the mesh, but in midurethral sling procedures typically removal of the mesh in the area where there's a problem usually has a fairly good ability to resolve the pain. At times there will still be some residual pain in the area that may need some additional treatment, but it is very unusual for you to have removed the mesh and/or, you know, incorporated tissue and have no change in the patient's pain complaints.

Q. What are the various treatments that are available when pain persists after the mesh is removed?

A. In my experience the, you know, the most sort of common things that we start with is ensuring that the tissue has -- is of good-enough quality, not atrophic, not inflamed or not having something like an

atrophic vaginitis as the cause of some of the irritation or discomfort, so we obviously -- we start with vaginal estrogen. It also helps promote healing from, let's say, having removed the mesh and trying to make better quality tissue.

Then if there -- depends a little bit on where the pain is located and how you elicit it, but if there is scar tissue that's there as residual or there is -- a lot of patients with pain issues have problems with tightness or spasms or call it a knot of their pelvic floor muscles, so physical therapy that involves manipulation of the scar tissue, they call it scar mobilization, there's techniques that they do, and/or myofascial treatment for the -- those two changes are usually very effective in resolving the problem.

If that isn't effective, then the next step we go to is perhaps a trigger-point injection into the scar tissue and/or we've even used Botox injections into the pelvic floor muscles that are in spasm.

Q. In your experience, Dr. Horbach, are all exposures or erosions of mesh symptomatic in the women you're caring for?

A. No. I will periodically have a patient referred to me because there is a small mesh exposure

that the general gynecologist or the internist has seen or felt during a routine examination and the patient may not be aware of it or have any symptoms from that, and that patient will then be referred in for treatment.

Those treatments can sometimes involve conservative management not having to do anything surgically. If it's a larger area of mesh that's exposed and doesn't respond conservatively, then occasionally it does require surgical intervention.

Q. Doctor, you described the gradual transition from the TVT Retropubic to the Boston Scientific product to the TVT Exact. Comparing the TVT Retropubic to the Exact, explain, if you would, what the similarities and differences of the two products are.

A. The product itself and essentially the mesh, assuming, you know, you'd do the laser-cut TVT Retropubic mesh, and the sleeve, they are essentially, you know, pretty much identical. Even if you use mechanical versus laser, the edges may be slightly different, although not typically something that affects, you know, your surgical procedure, but the mesh and the porosity and the handling of the mesh is very, very similar.

It's really more the difference between the -- sort of the ends of what's attached to the mesh that is different and how you actually are -- what -- what type of instrument you're using to actually pass the mesh into its position, but the position where you're inserting the mesh is the same through each of the two procedures. You are tensioning it in the same way. You know, risk issues are fairly much the same. I mean, you're really -- it's more the parts that stick on the end that's the issue that's different.

Q. Are they ultimately removed, the parts that stick on the end?

A. Yes. Yes. Sorry. Sorry.

Q. Do both of those meshes consist of polypropylene?

A. Yep, both of the TVT Retropubic and the Exact are polypropylene.

Q. Are they the same length ultimately?

A. Yes.

Q. Do they involve the same amount of mesh being left within the -- inside of the patient?

A. Yes. If you were to implant either one in the same patient, it's still the same length and amount left behind.

Q. Is it implanted through the exact same part

of the body, both the -- both the Retropubic and the Exact?

A. Yes, same vaginal incision, essentially same suprapubic incision, maybe a millimeter or two different, and same pathway and tunneling that you do.

Q. What caused you to use the Exact over time as opposed to the Retropubic?

A. I think part of it is surgeons, especially reconstructive surgeons, we're always trying to figure out, you know, do we like this versus that, is this one better, that one better in our hands and handling it. Do we, you know -- and part of what we do in our practice is we also teach a fair amount. We are involved with fellowship training, so part of our -- whether we choose one thing or another is to expose our fellows to a variety of different ways of treating it. Because if they're going to go out, especially our military fellows, that go out to a community or a smaller hospital or sort of a more isolated area, they may have only one thing that they have available versus the other.

So I think it was for me more just a little bit of a personal preference. The introducer in one is metal; the other one is plastic. I mean, there are really not a huge amount of difference. One is white;

the other is metal. So, you know, can you see one or the other more easily if you're looking inside the bladder.

So I think that's part of the reason that I, you know, made my transition. It's not anything to do with the mesh itself. And actually whether I use Boston Scientific or Exact or Retropubic, really it's not related to what I'm actually implanting. It is one's blue and the other thing is white, and one's white and the other thing is blue, and which one, you know, you may prefer to use.

I don't think that there is any ultimate clinical difference in the outcome of the two products with patients. In fact I was actually, you know, initially a little concerned when I went to the TVT Exact versus a slightly larger trocar that, although it was a smaller trocar, it might change my tactile ability to pass this, and, you know, is it going to be too easy to pass and you're going to lose that sensation.

So you're always just trying to find something that for you personally works the best. And since obviously one of my partners uses one, one of the partners uses the other, I sort of mix and match. We haven't really seen a clear difference between the

ultimate outcome in the different products, which is why we don't all do it exactly with one product.

Q. And when you talk about the ultimate outcome, you're talking about the complications that may occur as a result of, you know, any one of those various techniques?

A. Yes, success and efficacy, also plus potential complications.

Q. You were asked some questions about the learning curve associated with the TVT Retropubic device. The more traditional methods of approaching stress incontinence, for example, the Burch or the autologous sling, do they have learning curves that are different from the learning curve associated with the TVT Retropubic?

A. I believe so, yes. I think that the autologous sling is probably the most difficult of all of those procedures relative to a learning curve because, you know, simply harvesting it, passing it, there's not some of the same variables you can use for inserting it. It requires a little more invasiveness to be able to obtain the sample, especially if you're using a rectus fascia. If you're using a fascia lata graft, then it has to be harvested, so that's more involved. The --

So the learning curve for, I think, a traditional suburethral sling is probably the highest. In Burch procedures, an open Burch procedure is, you know, a moderately difficult procedure to do because the position that you have to be in, you know, stitching, you have to be able to sew essentially pretty much with one hand in the vagina holding up the tissue and another hand where you're going in the abdomen. So it requires the surgeon to be much more skilled at sewing one-handed, being able to get into the retropubic space and working in a very small area, especially if you're trying to do a small incision, is very -- is more challenging. And the Burch done as a laparoscopic procedure is probably one of the most difficult laparoscopic procedures we do in our field. It is even more challenging, let's say, than a laparoscopic sacrocolpopexy.

Q. You were asked some questions about factors that may lead to mesh exposure. And, Dr. Horbach, is lack of vaginal rest something that can lead to a mesh exposure? And in answering that, would you explain what vaginal rest is?

MR. GRAND: Objection.

THE WITNESS: We use the term vaginal rest with our patients postoperatively to mean you don't

put anything in your vagina for a period of time and whether that is tampons or douching or sexual intercourse. So that if a patient were to do any of those things, especially the intercourse portion because that puts more stretch, during sort of too early prior to adequate healing, you could pull open or tear any of the tissue and potentially increase the risk of an exposure.

BY MS. WAHRENBERGER:

Q. Doctor, is it basic knowledge that pain can be chronic or temporary?

A. Absolutely. Both surgical, you know, any physician knows that essentially pain can be chronic or temporary, and surgeons certainly are aware that what they do with an operation and with cutting can result in temporary pain in the acute postoperative period or chronic pain in the long term.

Q. Is that medical knowledge, that is, that pain can be either temporary or chronic, applicable also to the pain that can be associated with sexual intercourse --

A. That --

Q. -- that it can be either temporary or chronic?

A. That pain with sexual intercourse can be

temporary or chronic? I think, yes, I think that information is known. It depends a little bit, again, on what the cause of the pain with intercourse is. If there is a reversible cause, then it's going to be more on a temporary basis. If it's potentially a nonreversible cause, then -- or the patient -- we sometimes have patients where we have given them options and they have chosen not to take those options, then it's going to be potentially chronic.

Q. Is it basic surgical knowledge -- excuse me -- that when an adverse reaction occurs, further surgery may become necessary to correct it?

MR. GRAND: Objection.

THE WITNESS: Yes. Any surgical discipline across the board, from day one of your training, you're aware that, if you have a complication from surgery, that it may require you to do additional surgery to correct it.

BY MS. WAHRENBERGER:

Q. Is it sometimes necessary to do more than one additional surgery depending upon the situation?

A. Unfortunately, yes, that is sometimes the case.

Q. Before you used the TVT Retropubic device, which you've told us you used for a number of years

before you started to use either the TVT Exact or the Boston Scientific sling, did you read the IFU that came with the package?

A. I actually never read the IFU prior to using the package.

Q. How did you know what the proper way to implant the device was and what the complications or potential adverse reactions were that were associated with it, if you never read the IFU?

A. I -- the -- knowing how to implant it or learning how to implant it was something that I learned, you know, more by demonstration, as I said, watching my partner and having my partner teach me more, I guess, the Kinesic, whatever, way of learning rather than reading specifically about it.

From the standpoint of potential complications associated with it, I had had a moderate amount of experience with use of Prolene mesh per se in other surgical procedures in the pelvis, and I certainly had had a fair amount of experience in doing sling procedures themselves and including sling procedures with synthetic materials.

So that the type of complications that were going to be specific for the TVT Retropubic weren't any different than really what my prior experience

clinically and operating had already indicated to me and/or my, you know, reading of the literature.

Q. And would that have gone back all the way to your training as a surgeon, that is, your residency training and your fellowship training?

A. Yes, more so probably in fellowship than per se residency, but, then, again, it depends on your residency and whether you have someone who does these types of procedures to be, you know, training you in the beginning.

Q. Is it your understanding that surgeons expect that a medical device's IFU will advise the doctor of all significant risks?

A. Yeah, I think that the expectation for the physician probably is that that would be included in an IFU, but, again, the majority of the physicians that I know, especially the surgeons that I know, will -- they're not going to begin to use a piece of equipment if they, you know, don't understand enough of what's going on. They're not going to go and rely just on the IFU as being their sole source of information, both in how to do it and why to do it and the potential risks involved in it. Most people, they have done their learning and their research and their education prior to ever, you know, getting in the

operating room to start using the device.

Q. The IFU itself is not expected to include every single solitary risk that could potentially occur, but rather the ones that are significant or material for the doctor to be aware of; is that the case?

A. I think that's --

MR. GRAND: Objection.

THE WITNESS: I think that's my understanding of, you know, what the IFU is designed to do. Again, surgeons may do surgery without ever looking at the IFU. So even if there never, I guess, was an IFU, you know, you're still potentially going to be doing the procedures, assuming that you have the appropriate knowledge and experience to potentially do that. It's not a prerequisite that you have to read the IFU and sign off on it or whatever before you can begin to do a surgical procedure.

BY MS. WAHRENBERGER:

Q. And the knowledge that the surgeon would be expected to have would be the various significant risks associated with a particular procedure, true?

A. Yes, that's what the knowledge that the surgeon should have prior to undertaking the procedure.

Q. What are the risks associated with pelvic floor surgery in your experience?

A. In discussing with patients, you know, risks of surgery, you know, pelvic floor primarily, you know, maybe stress incontinence issues, is we talk about the risk of bleeding during surgery, that the risk of bleeding is infrequently or rarely going to be sufficient to cause a health compromise to the patient that could require anything like a transfusion.

We talk about the risk of infection that is more in the immediate time period from the standpoint of incisional infections or abscesses or the possibility, especially in the post-op time of, let's say, urinary tract infection if the patient has to wear a catheter for a more extended period of time.

We talk about the risks of injury to the adjacent organs that we are operating nearby, including the urethra, the bladder, the ureters, the bowel, the major blood vessels in the area, or some of the major nerves in the area.

We talk about, you know, pain with -- in the short-term postoperatively and in the long-term postoperatively. We talk about risk of persistent stress incontinence or, theoretically, even worsening stress incontinence, the development of urge

incontinence, overactive bladder, or if the -- de novo essentially -- or if the patient has mixed incontinence that, following surgery, the mixed incontinence can, in some small number of women, it can get better. Most of the women probably there's not a major change, and in a small number of women it can get worse, and that that can require the patient to undergo further treatment.

We talk about there could be voiding abnormalities or voiding dysfunction that could be minor changes versus significant enough to require further surgery to release the sling.

We talk about the risk of erosion into the vaginal tissues, the urethra, or bladder that, again, could require additional surgery.

We talk about obviously medical risks associated with surgery, from health issues, you know, that type of thing.

Trying to think of anything ... I mean, those are, at least in our -- even for our practice, those are already preprinted on the consent form as we go through that and have the patient signing the consent form.

MS. WAHRENBERGER: We're going to change the tapes.

VIDEO SPECIALIST: The time now is 2:45. We are going off the record.

(Proceedings recessed.)

VIDEO SPECIALIST: The time now is 2:46. We are back on the record.

BY MS. WAHRENBERGER:

Q. Do you talk about anesthesia risks?

A. Yes. Thank you. I do discuss anesthesia risks with the patient, and those risks are going to differ depending upon which procedure I do and which type of anesthesia might be necessary -- whether it's general anesthesia, with intubation, such as, you know, typically a Burch, and especially a laparoscopic Burch, regional anesthesia for open Burches and autologous slings, and typically IV sedation or, let's say, local anesthesia with or without IV sedation for a midurethral sling.

Q. We've already talked about the possible need for reoperation. Is that something you discuss with patients?

A. Yes, that's actually something we discuss with any patient who we're doing -- any type of reconstructive surgery on, whether it's incontinence, prolapse or a combination of both.

Q. Do you talk about the possibility of

pulmonary embolus or deep vein thrombosis, things of that sort?

A. Yes. Actually on our consent we have blood clots listed as a potential risk, and we talk about the steps that we do to try to reduce the likelihood of DVT or pulmonary embolus from the surgery.

Q. You mentioned erosion that you speak with your patients about. Does that occur only with synthetic slings?

A. No. You can see erosion with -- when permanent sutures are used that can erode through the vagina or into the bladder and you can see erosion with -- into the vagina, bladder, urethra, with any of the biologic materials.

With autologous fascia, you can see vaginal erosions maybe a little bit less, but you could certainly see urethral and bladder erosions even with autologous tissue.

Q. All of the risks that we've just discussed in the last few minutes, are they things that a trained doctor needs to read an IFU to know about?

A. I hope not. I would not expect so. I mean, these are things --

MR. GRAND: Objection.

THE WITNESS: -- that you would -- these

are things you would need to -- that you would learn during your residency and, you know, probably wouldn't pass your boards if you were not aware of these things, even as a general ob/gyn.

BY MS. WAHRENBERGER:

Q. Dr. Horbach, do you believe that the mesh that's used in the TVT Retropubic product is the state of the art?

A. From the standpoint of mesh itself in these -- in the midurethral slings, yeah, I think it is absolutely the best alternative and option that we've had for treating women, you know, for stress incontinence for years. I mean, it's the one typical thing that has stood more of a test of time than some of the other materials that we have used in the past in terms of, again, risk, you know, benefit profile for the patients, yeah.

Q. Would you agree that the TVT Retropubic device is the most studied SUI sling on the market?

A. I personally think --

MR. GRAND: Objection.

THE WITNESS: I think that the data would show that midurethral slings in general are the most studied incontinence procedure that we have period, and that, based on the number of Ethicon slings that

are done versus other companies, there's more data specifically on the Ethicon product than there are on the other products.

BY MS. WAHRENBERGER:

Q. Have you read any randomized control trials that indicate that the TVT mesh either degraded or was determined to be cytotoxic?

A. No.

Q. Have you seen erosions in the left lateral sulcus?

A. With --

Q. Ever.

A. Yes, I have seen erosions in the left periurethral, left sulcus area, yes.

Q. With any particular product do you see those erosions?

A. In my experience I have only seen them when an obturator sling has been done, a trans -- a transobturator sling, not when a retropubic sling has been done.

MS. WAHRENBERGER: I think that's all I have. Thank you.

MR. GRAND: I have a few follow-up questions, doctor.

EXAMINATION (continued)

BY MR. GRAND:

Q. Could a clinically significant inflammation cause an erosion?

A. A clinically significant inflammation could lead to an erosion. I'm not sure whether you could say it's causative, but you could see that as a sequelae of a clinically significant inflammation.

Q. Okay. With respect to -- you were asked some questions by counsel about foreign-body response. Do you recall that?

A. Yes.

Q. Okay. Would it be fair to say that the foreign body -- the foreign-body response to a piece of suture would not be the same as the foreign-body response to a piece of -- a much larger piece of mesh?

A. If you're talking about -- yeah, I mean, again, if it's a difference in the size and volume of the material, I think the foreign-body reaction will extend over more space if the material is over more space than if it's under less space -- over less space. Makes sense ...

Q. And you were asked some questions earlier asking you to discuss the differences or similarities between the TVT Retropubic and the TVT Exact. Do you recall that?

A. Yes.

Q. Okay. There have been some -- there are some differences in the procedure between the TVT Exact and the TVT Retropubic, correct?

MS. WAHRENBERGER: Object to the form of the question.

THE WITNESS: Yeah, I -- I think I would need you to be more specific about what you mean with the differences in the procedure.

BY MR. GRAND:

Q. Are you aware of any differences between the procedure described in the IFU between the TVT Exact and the TVT Retropubic?

MS. WAHRENBERGER: Do you mean how it's implanted, by "procedure"?

MR. GRAND: Are you -- are you testifying, counsel?

MS. WAHRENBERGER: No, no, I'm just trying to understand your question.

THE WITNESS: Your -- you do different --

MR. GRAND: She didn't say she couldn't understand it.

MS. WAHRENBERGER: Yes, she did.

MR. GRAND: And I rephrased it, and before she could answer you interrupted.

MS. WAHRENBERGER: It still wasn't clear.

THE WITNESS: Let me try to answer what I think you're asking me, and hopefully this is --

MS. WAHRENBERGER: Well, if you don't understand it, just say that.

BY MR. GRAND:

Q. Doctor, I'll withdraw the question and I'm going to re-ask it.

Are you aware of any differences in the procedure for implanting a TVT-R and a TVT Exact as described in the IFU for the product? Strike that. Let me rephrase it.

The TVT-R -- strike that.

The procedure for implanting the TVT-R at the time you first began using it in 2003 is different from the procedure to implant the TVT Exact as described in the current IFU; is that correct?

A. You know, I mean, there are differences in how it shows on the IFU, how you attach this and how you attach that and the size of incisions that you make, et cetera. So, yes, I guess there are differences.

Q. And the warnings that accompany -- the warnings of the TVT are -- today -- are different than the warnings that accompanied the TVT-R when you first

began using the product, correct?

MS. WAHRENBERGER: Object to the form of the question.

THE WITNESS: Yes, the current IFU is differently -- there are different wording in that versus the original.

BY MR. GRAND:

Q. And those same warnings are contained in the IFU for the Exact today, correct?

MS. WAHRENBERGER: Objection to the form of the question.

THE WITNESS: The same warnings from the original or the same warnings from the current?

BY MR. GRAND:

Q. Have you compared -- strike that. I don't need to ask that.

You were asked a question about whether the TVT-R reflects the state of the art. Do you recall that?

A. Yeah, I think that was the term. Yes.

Q. Okay. Do you have an understanding of what that term means in a legal sense?

MS. WAHRENBERGER: Objection to the form of the question.

THE WITNESS: I have an understanding of

what it means in the medical sense in terms of what we consider state of the art. I'm not sure if that's the same definition legally.

BY MR. GRAND:

Q. Have you ever designed a mesh sling?

A. I have -- I guess I would say in some ways, yes. It -- when I began using Gore-Tex or a polytetrafluoroethylene for slings, we fashioned and created the slings ourselves, yes.

Again, your question, have I -- did I design the material of the sling? No. Did I design the sling and shape it and create it the way that I wanted to, to use in the operating room? Yes.

Q. Okay. Have you ever designed a mesh sling for use by other doctors?

A. No.

Q. Have you read any of the design documents created by Ethicon in its development of the TVT-R?

A. I did a long time ago, so I wouldn't be able to recall the specifics.

Q. Okay. Do you have any idea of what the different considerations were undertaken by Ethicon in its design of the TVT-R?

MS. WAHRENBERGER: Objection to the form.

THE WITNESS: Again, I -- I'd have to look

back at the documents to be able to specify.

BY MR. GRAND:

Q. Doctor, do you hold yourself out as an expert on the design of medical devices?

A. I am not a material engineer, no.

Q. And at the time --

A. I'm not a biomedical engineer -- sorry -- or a biomedical engineer, yes, I'm not that.

Q. At the time that the TVT was implanted in Mrs. Corbet in this case, which I'm going to represent to you was 2011, do you have any idea of what other design alternatives were available to Ethicon for its midurethral slings?

A. My understanding is that they looked at other materials to consider as alternatives to the mesh that was used in 2011.

Q. Your understanding is that in 2011 you have an understanding as to -- strike that.

Do you have any idea in the year 2011 what other -- what design options were available to Ethicon for its midurethral slings?

MS. WAHRENBERGER: This was just asked and answered.

THE WITNESS: Yes, I do have an understanding of some of the different design issues

that came into play. I mean, they -- the discussion was -- can't find it -- one of the issues, because they developed it around that time period, was the TVT Secur that was to ideally be a single-incision sling, avoid having to place --

BY MR. GRAND:

Q. Doctor, I'm sorry to interrupt you, but I'm not asking you about -- I'm asking you about what options were available to them in 2011, not historically before that.

A. Okay.

MS. WAHRENBERGER: So you're asking if she knows what the options were available to Ethicon in 2011 --

BY MR. GRAND:

Q. Yes. Do you know if Ethicon --

MS. WAHRENBERGER: -- for mesh design.

BY MR. GRAND:

Q. -- had other materials?

A. Yes.

Q. Do you have any idea whether Ethicon had other materials they could have used in a midurethral sling in 2011?

A. Thank you. That clarifies it. I'm sorry. Yes, I am aware that Ethicon had other materials that

it could use for the sling.

Q. What materials were those?

A. The question was whether or not -- they looked at the use of Ultra Pro, a combination, sort of a multifilament mesh that combined absorbable suture with -- absorbable fibers, Monocryl, plus the polypropylene fibers. So that was one of the materials they had and looked at as an option for their sling material. They also had Vypro as an alternative material to consider using at that time as well. Those two I'm -- I'm aware that they had.

Q. Doctor, I'm sorry, I need about ten minutes for a telephone call, and then I just have like one or two more questions.

A. Okay.

MR. GRAND: But the Court is waiting.

VIDEO SPECIALIST: The time now is 3:03. We are going off the record.

(Proceedings recessed.)

VIDEO SPECIALIST: The time now is 3:32. We are back on the record.

BY MR. GRAND:

Q. Dr. Horbach, you were asked questions by counsel regarding cytotoxicity. Do you recall that?

A. I don't recall that we talked about

cytotoxicity.

Q. Okay. Have you reviewed any internal documents relating to cytotoxicity of Prolene mesh?

A. I've reviewed documents regarding that. I think some of them perhaps were Ethicon and then some additional -- some additional information in the literature.

Q. Okay. Do you have any opinions on whether or not the Prolene mesh that's used in the TVT Retropubic is cytotoxic?

A. Well, again, cytotoxicity from the standpoint -- I don't think that it has a risk of -- or significant -- well, I don't think that it has issues related to carcinogenic potential from the standpoint of any type of cytotoxicity.

Q. Thank you, doctor. I don't have any further questions.

MS. WAHRENBERGER: Okay. I just have a couple. I'd like to go back to the questions you asked, Jeff, about the Ultra Pro and the Vypro, that series of questions.

EXAMINATION (resumed)

BY MS. WAHRENBERGER:

Q. Dr. Horbach, when you were answering questions about these two products, was it your

opinion or was it your intention to suggest that these were alternative designs that could have been utilized as the mesh product that would be part of a sling that could be implanted in a woman successfully, safely and efficaciously?

A. My comments about other products or other materials, I think, that Ethicon had was that Ethicon manufactured other types of mesh material, and Ethicon actually around that time period, I think, starting in 2010, even looked at alternative mesh materials for its minimally invasive sling. One was the use of the Ultra Pro to give less -- less long-term permanent mesh fibers present, and that, with investigation, was found to not work as effectively in the sling situation because of the outer sheaths being sort of stuck or partially -- having more difficulty with removal and requiring more tension that placed the mesh suburethrally under more tension. So they were concerned about use of that.

Plus there had been some additional work looking at use of the Ultra Pro in more of a patch-type of sling situation, and it still had very similar erosion rates associated with it compared to what was designed for the original -- or designed with the typical Prolene mesh. Plus Ultra Pro hadn't been

FDA approved for use of -- in stress incontinence per se.

They also had Vypro as an alternative with an absorbable mesh, again, not FDA approved for this indication, but the limited amount of studies that I could find regarding any attempt at using that as a sling actually showed even more problems with reactivity in that material than even in the Ultra Pro or the standard Prolene that they were using for their mesh.

Q. Doctor, and do you explain the full extent of your opinion regarding these alternative substances that might have been considered for use as part of a sling in your supplemental report, the report that was dated December 15th, 2015?

A. Yes, I do.

Q. And beginning on page 24 under category D for the next three or four pages, all the way actually until page 29, is there a detailed discussion in your report of why these products that were available were determined not to be --

A. Optimal?

Q. Well, not to be --

A. Chosen?

Q. Just get the correct term -- not to be

either practical or technically feasible alternative designs?

A. Yes, in my supplemental report, as part of my response to some of the plaintiff's experts' allegations, I did discuss the possibility of other materials being used for the pros and cons.

MS. WAHRENBERGER: Thank you. That's all I have.

MR. GRAND: I have nothing further. Thank you, doctor.

VIDEO SPECIALIST: The time now is 3:38. This deposition has concluded.

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(The deposition of NICOLETTE S. HORBACH, M.D. adjourned at 3:38 p.m.)

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E R R A T A

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ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

NICOLETTE S. HORBACH, M.D. DATE

Subscribed and sworn
to before me this
_____ day of _____, 20____.
My commission expires:_____

_____

Notary Public

C E R T I F I C A T E

I, LINDA S. KINKADE, Registered Diplomate Reporter, Certified Realtime Reporter, Registered Merit Reporter, Certified Shorthand Reporter, and Notary Public, do hereby certify that prior to the commencement of examination the deponent herein was duly sworn by me to testify truthfully under penalty of perjury.

I FURTHER CERTIFY that the foregoing is a true and accurate transcript of the proceedings as reported by me stenographically to the best of my ability.

I FURTHER CERTIFY that I am neither counsel for nor related to nor employed by any of the parties to this case and have no interest, financial or otherwise, in its outcome.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my notarial seal this 25th day of December 2015.

My commission expires: July 31, 2017

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NOTARY PUBLIC IN AND FOR
THE DISTRICT OF COLUMBIA